



**Australian Government**

**Department of Health**

***Therapeutic Goods Act 1989***

**Medicines Advisory Statements Specification 2016**

I, Mary McDonald, First Assistant Secretary, Medicines Regulation of the Regulatory Services Group and delegate of the Minister for Health, make this Specification under subsection 3(5A) of the *Therapeutic Goods Act 1989*.

Dated this 24 day of November 2015

(Signed by)

Mary McDonald  
Delegate of the Minister for Health

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## Introduction

This Specification sets out advisory statements that are required to be included on the labels of medicines to which the Specification applies, if they contain particular ingredients (in most cases, this relates to active ingredients only).

The advisory statements set out in the Specification are designed to address specific risks related to the use of medicines that have been identified via pharmacovigilance activities, testing, adverse event reports or other scientific or clinical information.

Having advisory statements on medicine labels therefore ensures that consumers are informed about these risks.

It is important to note that medicines that are mentioned in Part 1 of Schedule 10 to the Regulations – which are comprised of prescription medicines and medicines such as medical gasses, radiopharmaceuticals and dialysis solutions – are not required to comply with the Specification.

The exclusion of these products reflects that access to prescription medicines is controlled by registered medical practitioners, and that information about the potential benefits and risks of a medicine is part of the consultation between patient and prescriber rather than needing to be included on a medicine's label. Also, the risk-benefit profile of such medicines may vary considerably from patient to patient.

In relation to radiopharmaceuticals and the like, in most cases these are not supplied directly to consumers but are utilised in a treatment setting such as a hospital.

In addition to the above, medicines that are not mentioned in Part 1 of Schedule 10 to the Regulations but for which the Secretary or her delegate has consented to their import, supply or export notwithstanding that they do not comply with a requirement to include an advisory statement on their label (and which comply with the terms of that consent), will also not be required to comply with the Specification.

## 1 Name of Specification

This Specification is the *Medicines Advisory Statements Specification 2016*

## 2 Commencement

This Specification commences on 1 January 2016.

## 3 Transitional Arrangements

(1) From the date of commencement of this Specification until the day 18 months after the date of commencement of this Specification, medicines in a prescribed class must comply with the requirements specified in Schedule 1 to this Specification.

Note 1: Nothing in (1) is intended to prevent a person from complying with the requirements in Schedule 2 in relation to a medicine in a prescribed class between the date of commencement of this Specification and the day 18 months after the date of that commencement, if they wish to do so.

(2) From the day 18 months after the date of commencement of this Specification, medicines in a prescribed class must comply with the requirements specified in Schedule 2 to this Specification.

## 4 Definitions

(1) In this Specification:

**Act** means the *Therapeutic Goods Act 1989*

**dermal use** means application to the skin primarily for localised effect

**divided preparation** means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules

**dosage unit** means an individual dose of a medicine for therapeutic use and includes a tablet, capsule, cachet, single dose powder or single dose sachet of powders or granules

**essential oils** means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. It also means:

- (a) oils of equivalent composition derived through synthetic means; or
- (b) compounded oils of equivalent composition comprising a mixture of synthetic and natural components

**external** in relation to the use of a medicine means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice

**internal use** means administration:

- (a) orally, except for topical effect in the mouth; or
- (b) for absorption and the production of a systemic effect,
  - (i) by way of a body orifice other than the mouth; or
  - (ii) parenterally, other than by application to unbroken skin

**Labelling Order** means the order in force made under section 10 of the Act and published on the Federal Register of Legislative Instruments, specifying general requirements for labelling of medicines

**listed medicine** means a medicine that is listed in the Register under sections 26 or 26A of the Act

**main label** means:

- (a) where there are two or more labels or two or more portions of a single label – that label or portion of the label where the product name is more or most conspicuously shown; or
- (b) where the product name is equally conspicuous on two or more labels or portions of a label –each such label or portion.

**medicine** has the same meaning as in the Act

**medicine in a prescribed class** means medicine in a class prescribed in the Regulations for the purposes of paragraph 3(5)(ca) of the Act

**MRDD** (*Maximum recommended daily dose*) is the maximum approved dose per day for a medicine used for its main indication in adults

**Regulations** means the *Therapeutic Goods Regulations 1990*

**signal heading** means the signal word or words relating to the Schedule of the SUSMP in which the substance is included and the purpose for which it is to be used, as shown in the following table:

<b>Schedule</b>	<b>Purpose</b>	<b>Signal Words Required</b>
2	For any purpose	PHARMACY MEDICINE
3	For any purpose	PHARMACIST ONLY MEDICINE
4	For human use	PRESCRIPTION ONLY MEDICINE
5	For any purpose	CAUTION
6	For any purpose	POISON
7	For any purpose	DANGEROUS POISON
8	For any purpose	CONTROLLED DRUG

**SUSMP** means the Standard for the Uniform Scheduling of Medicines and Poisons, as set out in Schedule 1 of the current Poisons Standard

**topical use** means application of a substance for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied

- (2) Unless the contrary intention appears, a reference to **a substance** in this Specification includes:
- a. that substance prepared from natural sources or artificially; and
  - b. where the substance is a plant (other than a plant referred to in Schedules 8 or 9 of the SUSMP), that plant or any part of that plant when packed or prepared for therapeutic use; and
  - c. every salt, active principle or derivative of the substance, including esters and ethers and every salt of such an active principle or derivative; and
  - d. every alkaloid of the substance and every salt of such an alkaloid; and
  - e. except where the stereoisomer is defined in the substance name (e.g. dextromethorphan), every stereoisomer of the substance and every salt of such a stereoisomer; and
  - f. a preparation or admixture containing any proportion of the substance,
- but does not include:
- g. a preparation or product included in Appendix A of the SUSMP; or
  - h. a substance included in Appendix G of the SUSMP at a concentration not exceeding the concentration specified in column 2 of that Appendix in respect of the substance; or
  - i. any other substance included in Schedules 1 to 6 of the SUSMP, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8 of the SUSMP.
- (3) Unless the contrary intention appears, where a **concentration, strength or quantity** is specified in this Specification in respect of a substance:
- a. if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in this Specification; and
  - b. the expression “one per cent” means:
    - i. in the case of a liquid preparation, 1 gram of the substance per 100 mL of the preparation; or
    - ii. in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation and

- iii. any expression of greater or lesser percentages shall have a corresponding meaning; and
- c. in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.

## **5 Medicines Advisory Statements**

The advisory statements mentioned in Schedule 1 and Schedule 2 are specified under subsection 3 (5A) of the Act for the purposes of paragraph 3(5)(ca) of the Act.

## **Schedule 1**

### **Required Advisory Statements for Medicine Labels No. 2**

#### **(section 5)**

## Schedule 1

### Required Advisory Statements for Medicine Labels No. 2

#### Advisory statements

Where a medicine:

- 1) includes a substance described in Column 1 of *Table 1: Medicines to Which Advisory Statements Apply* ('the table'), below; and
- 2) meets the condition(s) described in Column 2 of the table;

the statement(s) set out in Column 3 of the table must be contained on the labels of the medicine in accordance with the Labelling Order, in a manner that is compliant with any applicable presentation requirement(s) set out below (the requirements are indicated in the table by the presence of the applicable alphabetical in square brackets, next to the statement or, in the case of a requirement to use upper case and/or bold face, by use of upper case and/or bold face letters in the statement itself).

Unless otherwise specified, the requirements apply only if the substance is included in the medicine as an active ingredient.

#### Permitted variation and combination of advisory statements

The wording of the statements specified in this document may be varied provided that the intent is not changed.

Where more than one statement is required, they may be combined to form simple sentences where appropriate, provided that the intent is not changed and that any additional requirements are also met.

#### Additional presentation requirements for some advisory statements

In some cases, additional requirements apply to advisory statements, such as font, letter size etc. Where such additional requirements apply, they are indicated in Column 3 of Table 1 below either by a letter in square brackets (e.g. [c]) or, in the case of a requirement to use upper case and/or bold face, by use of upper case and/or bold face letters in the statement itself. The meaning of the letters is set out below:

[c]: Statement(s) must be included at the beginning of the directions for use.

[f]: Statement(s) must be included on the label written:

- (i) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN"; and
- (ii) in bold-face sanserif capital letters of uniform thickness; and
- (iii) in letters as least four tenths the height of the letters used for the signal heading; and
- (iv) with nothing else besides the statement written on the same line.

[g]: Statement(s), written in sanserif capital letters, must be included on the main label or as part of the directions for use.



[k]: Statement(s) must be printed in type of 3 mm height or larger.

[l]: Statement(s) must be printed on the front of the goods.

**Note: Meaning of notes in Column 1 of the table**

To assist sponsors to prepare for compliance with amended requirements in Schedule 2 to the *Medicines Advisory Statements Specification 2016*, the following Note is included in Column 1 of the table, where applicable: '*NB: entry amended in Schedule 2*'.

**Table 1: Medicines to which advisory statements apply**

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Acetone	In concentrations greater than 75 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Avoid breathing [vapour/spray mist]</li> </ul> </li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>
<i>Actaea racemosa</i>	In listed medicines	<ul style="list-style-type: none"> <li>• <b>Warning:</b> In very rare cases, Black cohosh has been associated with liver failure.</li> <li>• If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.</li> </ul>
Activated charcoal	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing activated charcoal should be used with caution in children since it may interfere with the absorption of nutrients.</li> <li>• This substance may interact with other medicines.</li> <li>• Activated charcoal is not recommended for long-term use.</li> </ul>
Ademetionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>
(S)-S-Adenosylmethionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Alclometasone	When included in Schedule 3 to the SUSMP	<ul style="list-style-type: none"> <li>• CAUTION - Do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Alpha casozepine enriched hydrolysed milk protein	In listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Alpha hydroxy acids, including: <ul style="list-style-type: none"> <li>• citric acid and other fruit acids</li> <li>• glycollic acid</li> <li>• lactic acid</li> </ul>	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>• Not recommended for use on children and infants.</li> </ul>
Amethocaine (Entry 1 of 2)	When included in Schedule 2 to the SUSMP and for dermal use	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Amethocaine (Entry 2 of 2)	For the purpose of exclusion from the schedules of the SUSMP when in dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Ammonia and ammonium salts, including</p> <ul style="list-style-type: none"> <li>• ammonium chloride</li> <li>• ammonium bicarbonate</li> <li>• ammonium carbonate</li> </ul> <p><i>(Entry 1 of 2)</i></p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years</p>	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
<p>Ammonia and ammonium salts, including</p> <ul style="list-style-type: none"> <li>• ammonium chloride</li> <li>• ammonium bicarbonate</li> <li>• ammonium carbonate</li> </ul> <p><i>(Entry 2 of 2)</i></p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)</p>	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
<p>Anise oil</p>	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations containing more than 50 per cent of anise oil; and</li> <li>b. packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines (Entry 1 of 5)	When included in a schedule to the SUSMP and NOT separately specified in the table and NOT: <ol style="list-style-type: none"> <li>a. dermal, ocular or paediatric preparations; or</li> <li>b. oral preparations of desloratadine, loratadine or fexofenadine; or</li> <li>c. nasal preparations of azelastine</li> </ol>	<p><i>either</i></p> <ul style="list-style-type: none"> <li>• This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>• This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul>
Antihistamines (Entry 2 of 5)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Antihistamines (Entry 3 of 5)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul> <p><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></p> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines (Entry 4 of 5)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Antihistamines (Entry 5 of 5), including: -Diphenhydramine -Doxylamine -Promethazine	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Arginine	In listed medicines	<ul style="list-style-type: none"> <li>• This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa, vagina or rectum.</li> </ul>
Aspartame	When for oral ingestion and included in medicines as an active or excipient ingredient	<ul style="list-style-type: none"> <li>• Phenylketonurics are warned that this product contains aspartame (phenylalanine).</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 1 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains MORE than 100 milligrams of aspirin; and</p> <p>b. the preparation is NOT indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 2 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains MORE than 100 milligrams of aspirin; and</p> <p>b. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 3 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains 100 milligrams OR LESS of aspirin; and</p> <p>b. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• For use under medical supervision only</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 4 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or</p> <p>b. in sustained release preparations containing 650 milligrams or more of aspirin</p>	<ul style="list-style-type: none"> <li>• For use under medical supervision only.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 5 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. the preparation IS indicated exclusively for treatment of dysmenorrhoea; and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. NOT in combination with other therapeutically active substances (other than effervescent agents)</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 6 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. in combination with other therapeutically active substances (other than effervescent agents); and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. the preparation is NOT indicated:</p> <p>i. for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or</p> <p>ii. exclusively for treatment of dysmenorrhoea</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 7 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. NOT in combination with other therapeutically active substances (other than effervescent agents); and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. the preparation is NOT indicated:</p> <p>i. for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or</p> <p>ii. exclusively for treatment of dysmenorrhoea</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>
Atropa belladonna	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>•</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Atropine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
<i>Azadirachta indica</i> (neem) (Entry 1 of 2)	When: <ul style="list-style-type: none"> <li>a. included in listed medicines; or</li> <li>b. for the purpose of exclusion from the schedules to the SUSMP when in preparations for dermal use and in a container fitted with a child resistant closure</li> </ul>	<ul style="list-style-type: none"> <li>• Not to be taken.</li> <li>• Keep out of reach of children.</li> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
<i>Azadirachta indica</i> including its extracts and derivatives (Entry 2 of 2)	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
Azelastine	In preparations for topical ophthalmic or nasal administration	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
<i>Backhousia citriodora</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Not recommended for use by children aged 12 years or under.</li> <li>• Not recommended for use by pregnant or lactating women.</li> <li>• If skin irritation occurs, discontinue use.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Basil oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations or oils containing more than 5 per cent of methyl chavicol; and</li> <li>b. packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Bay oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations containing more than 25 per cent of bay oil; and</li> <li>b. packed in containers having: <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Benzocaine (Entry 1 of 3)	In dermal preparations containing MORE than 2 per cent of total local anaesthetic substances	<ul style="list-style-type: none"> <li>Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Benzocaine (Entry 2 of 3)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Benzocaine (Entry 3 of 3)	In lozenges	<ul style="list-style-type: none"> <li>Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth.</li> <li>Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.</li> </ul>
Benzoyl peroxide	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>Keep from eyes, lips, mouth and sensitive areas of the neck.</li> <li>If excessive swelling, irritation, redness or peeling occurs, discontinue use.</li> <li>If these persist, consult a physician.</li> <li>Avoid excessive exposure to sunlight and other sources of ultra violet light.</li> </ul>
Benzydamine	In preparations for topical use or dermal use	<ul style="list-style-type: none"> <li>Do not use [this product/<i>insert name of product</i>] if you are allergic to benzydamine or other anti-inflammatory medicines.</li> <li>If you get an allergic reaction, stop taking and see your doctor immediately.</li> </ul>
Bergamot oil	For the purpose of exclusion from the schedules to the SUSMP; or when included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>Application to skin may increase sensitivity to sunlight.</li> </ul>
Bovine colostrum powder	In listed medicines	<ul style="list-style-type: none"> <li>Products containing bovine colostrum powder contain lactose and cow's milk proteins.</li> <li>This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Bovine lactoferrin	In listed medicines	<ul style="list-style-type: none"> <li>Derived from cow's milk.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Bovine whey IG-rich fraction	In listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Bromhexine <i>(Entry 1 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Bromhexine <i>(Entry 2 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner .</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Brompheniramine <i>(Entry 1 of 3)</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Brompheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Brompheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Butoconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Do not use if you are pregnant.</li> <li>• See a doctor before use if you are diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Caffeine (Entry 1 of 2)	In listed medicines, except medicines containing less than 1 milligram of caffeine in the MRDD: <ol style="list-style-type: none"> <li>a. for oral or sublingual administration; and</li> <li>b. the MRDD of which contains 10 milligrams OR LESS of caffeine or less; and</li> <li>c. when the caffeine is from a herbal source</li> </ol>	<ul style="list-style-type: none"> <li>• The recommended dose of this medicine provides small amounts of caffeine.</li> </ul>
Caffeine (Entry 2 of 2)	In listed medicines: <ol style="list-style-type: none"> <li>a. for oral or sublingual administration; and</li> <li>b. the MRDD of which contains MORE THAN 10 milligrams of caffeine; and</li> <li>c. when the caffeine is from a herbal source</li> </ol>	<ul style="list-style-type: none"> <li>• Contains [<i>amount of caffeine in milligrams</i>] mg of caffeine.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cajuput oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations or oils containing more than 25 per cent of cajuput oil; and</li> <li>b. packed in containers having:               <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Calcium sodium caseinate	In listed medicines	<p><i>either</i></p> <ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>• Contains cow's milk protein.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Camphor (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. included as a natural component in essential oils containing greater than 2.5 per cent of camphor but 10 per cent or less of camphor; and</p> <p>b. packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</p>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> <li>• Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Camphor (Entry 2 of 3)	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>a. in essential oils when the camphor is present as a natural component of the oil; and</li> <li>b. packed in containers having:               <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> <li>• Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.</li> </ul>
Camphor (Entry 3 of 3)	When: <ol style="list-style-type: none"> <li>a. included in a schedule to the SUSMP, and</li> <li>b. not in block, ball or pellet form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.</li> </ol>	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> <li>• <b>SAFETY DIRECTIONS</b> Can be fatal to children if sucked or swallowed. Avoid contact with eyes.</li> </ul>
<i>Canarium indicum</i>	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains material derived from nuts.</li> </ul>
<i>Carthamus tinctorius</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cassia oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with skin.</li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Cetirizine (Entry 1 of 2)	In preparations for oral use that are NOT specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Cetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• This medication may cause drowsiness.</li> </ul>
Charcoal – activated	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing activated charcoal should be used with caution in children since it may interfere with the absorption of nutrients.</li> <li>• This substance may interact with other medicines.</li> <li>• Activated charcoal is not recommended for long term use.</li> </ul>
<i>Chelidonium majus</i>	When the preparation is for oral use.	<ul style="list-style-type: none"> <li>• Warning: Greater Celandine may harm the liver in some people.</li> <li>• Use only under the supervision of a healthcare professional.</li> </ul>
Chitosan (Entry 1 of 2)	In listed medicines, except in oral powder dosage form.	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> <li>• Chitosan should be taken at least one hour after any other medication as it may reduce the effect of other medication.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chitosan (Entry 2 of 2)	In listed medicines in oral powder dosage form.	<ul style="list-style-type: none"> <li>Derived from seafood.</li> <li>Chitosan should be taken at least one hour after any other medication as it may reduce the effect of other medication.</li> <li>Do not take powder alone. Mix with food or fluid.</li> </ul>
Chlorhexidine (Entry 1 of 2)	In topical products, including preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> <li>Avoid contact with eyes.</li> <li>If in eyes, rinse well with water.</li> <li>WARNING – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs.</li> </ul>
Chlorhexidine (Entry 2 of 2)	In topical products OTHER THAN preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> <li>Avoid contact with eyes.</li> <li>If in eyes, rinse well with water.</li> <li>Mild irritation may occur; stop use if it becomes severe.</li> </ul>
Chlorpheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li>This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>Do not give to children under 12 years of age.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chlorpheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Chlorpheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Choline salicylate	In preparations for topical oral use.	<ul style="list-style-type: none"> <li>• Do not exceed the recommended dose. Excessive or prolonged use can be harmful.</li> </ul>
Chromates (including dichromates) of alkali metals or ammonia	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Avoid breathing [dust]/[vapour]/[ spray mist].</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cimetidine  <i>NB: entry amended in Schedule 2</i>	In Schedule 3 to the SUSMP	<ul style="list-style-type: none"> <li>• Use only under medical supervision if you are taking other medicines.</li> <li>• CAUTION: This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> </ul>
Cinchocaine <i>(Entry 1 of 2)</i>	In preparations for rectal use only	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Cinchocaine <i>(Entry 2 of 2)</i>	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Cineole	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations or oils containing more than 25 per cent of cineole (other than rosemary oil or camphor oil); and</li> <li>b. packed in containers having: <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cinnamon bark oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with skin</li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Cinnamon leaf oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. in preparations containing more than 25 per cent of cinnamon leaf oil; and</p> <p>b. packed in containers having:</p> <p>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</p> <p>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</p>	<ul style="list-style-type: none"> <li>• <b>KEEP OUT OF REACH OF CHILDREN.</b></li> <li>• <b>NOT TO BE TAKEN.</b></li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Citric acid and other fruit acids <i>(See also Alpha hydroxy acids)</i>	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>• Not recommended for use on children and infants.</li> </ul>
Clobetasone	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> <li>• CAUTION - Do not use for children under 12 years old unless a doctor has told you to.</li> </ul>
Clotrimazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Clove oil (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>a. in preparations containing more than 25 per cent of clove oil; and</li> <li>b. packed in containers having:               <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Clove oil (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>
Coal tar	In preparations for topical use	<ul style="list-style-type: none"> <li>• Avoid contact with eyes.</li> <li>• If skin irritation occurs, discontinue use.</li> <li>• Do not use for prolonged periods except on the advice of a doctor or pharmacist.</li> </ul>
Codeine (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Codeine (Entry 2 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li><i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Colostrum powder – bovine	In listed medicines	<ul style="list-style-type: none"> <li>Products containing bovine colostrum powder contain lactose and cow's milk proteins.</li> <li>This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Concentrated omega-3-triglycerides - squid	In listed medicines	<ul style="list-style-type: none"> <li>DERIVED FROM SEAFOOD</li> </ul>
Creatine	In listed medicines	<ul style="list-style-type: none"> <li>Seek professional advice before long term use.</li> </ul>
Creatine monohydrate	In listed medicines	<ul style="list-style-type: none"> <li>Seek professional advice before long term use.</li> </ul>
Creatine phosphate	In listed medicines	<ul style="list-style-type: none"> <li>Seek professional advice before long term use.</li> </ul>
<i>Datura spp</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
Desloratadine	In medicines for oral use	<ul style="list-style-type: none"> <li>If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Dexchlorpheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li>This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dexchlorpheniramine  <i>(Entry 2 of 3)</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Dexchlorpheniramine  <i>(Entry 3 of 3)</i>	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Dextromethorphan <i>(Entry 1 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dextromethorphan <i>(Entry 2 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Diclofenac <i>(Entry 1 of 4)</i>  <i>NB: entry amended in Schedule 2</i>	In preparations for oral use when indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Diclofenac (Entry 2 of 4)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>In preparations for oral use in adults and children aged 12 years and over, when NOT indicated exclusively for the treatment of dysmenorrhoea</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac <i>(Entry 3 of 4)</i>  <i>NB: entry amended in Schedule 2</i>	In preparations indicated for oral use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>
Diclofenac <i>(Entry 4 of 4)</i>	When the preparation is for dermal use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.</li> </ul>
Diethyltoluamide (DEET)	All, including where present as an excipient	<ul style="list-style-type: none"> <li>• WARNING - May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.</li> </ul>
Dihydrocodeine <i>(Entry 1 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dihydrocodeine <i>(Entry 2 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Diphenhydramine <i>(Entry 1 of 4)</i>	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Diphenhydramine <i>(Entry 2 of 4)</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diphenhydramine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Diphenhydramine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Diphenoxylate	In medicines for oral use	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Doxylamine (Entry 1 of 4)	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Doxylamine (Entry 2 of 4)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Doxylamine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Doxylamine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Econazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Eucalyptus oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations containing more than 25 per cent of eucalyptus oil; and</li> <li>b. packed in containers having: <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Eugenol (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>a. in preparations containing more than 25 per cent of eugenol; and</li> <li>b. packed in containers having:               <ol style="list-style-type: none"> <li>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol> </li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Eugenol (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> <li>• DO NOT SWALLOW. [g]</li> </ul>
<i>Fallopia multiflora</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Warning: <i>Fallopia multiflora</i> may harm the liver in some people.</li> <li>• Use under the supervision of a healthcare professional.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Famciclovir	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are taking other medicines regularly, consult your pharmacist or doctor before use.</li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you are allergic to famciclovir or penciclovir.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you have problems with your immune system.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you have kidney problems, unless advised by a doctor.</li> <li>• If you have high blood pressure, heart problems, liver problems, diabetes or other medical conditions, consult your pharmacist or doctor before use.</li> <li>• If you have symptoms and signs of an infection other than your cold sore, consult your pharmacist or doctor before use.</li> </ul>
Famotidine  <i>NB: entry amended in Schedule 2</i>	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> </ul>
Fexofenadine	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Fluconazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> <li>• See a doctor before use if you are diabetic.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Fluorides (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. in listed medicines for dental use (pastes, powders or gels for cleaning the teeth) containing more than 1,000 mg/kg of fluoride ion; or</p> <p>b. in dental hygiene products (other than pastes, powders or gels for the cleaning of teeth) containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 milligrams total fluoride fitted with a child-resistant closure</p>	<ul style="list-style-type: none"> <li>• Do not swallow.</li> <li>• Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> </ul>
Fluorides (Entry 2 of 3)	When included in a schedule to the SUSMP except oral fluoride supplements	<ul style="list-style-type: none"> <li>• Do not swallow.</li> <li>• Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> </ul>
Fluorides (Entry 3 of 3)	In Schedule 2 to the SUSMP in oral preparations as fluoride supplements	<ul style="list-style-type: none"> <li>• Do not use if pregnant</li> <li>• Use of this product is not necessary in areas supplied with fluoridated water</li> <li>• Do not use except on the advice of a dentist</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Flurbiprofen (Entry 1 of 2)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>In oral preparations that do NOT include indications for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to flurbiprofen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Flurbiprofen <i>(Entry 2 of 2)</i>  <i>NB: entry amended            in Schedule 2</i>	In oral preparations that include indications for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to flurbiprofen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>
Folic acid	In preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects	<ul style="list-style-type: none"> <li>• Do not exceed the stated dose except on medical advice.</li> <li>• If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice.</li> </ul>
Glucosamine hydrochloride	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>
Glucosamine sulfate	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>
Glucosamine sulfate potassium chloride complex <i>(Entry 1 of 2)</i>	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Glucosamine sulfate potassium chloride complex (Entry 2 of 2)	In listed medicines for oral use	<ul style="list-style-type: none"> <li>• Keep out of reach of children.</li> <li>• Contains [<i>amount of potassium</i>] potassium.</li> <li>• If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> </ul>
Glucosamine sulfate sodium chloride complex	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>
Glycollic acid (See Alpha hydroxy acids)	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>• Not recommended for use on children and infants.</li> </ul>
Guaifenesin (Guaiphenesin) (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Guaifenesin (Guaiphenesin) (Entry 2 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hexachlorophane	In preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	<ul style="list-style-type: none"> <li>• For external washing only.</li> <li>• Rinse skin thoroughly after use.</li> </ul>
High selenium yeast	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Honey	In listed medicines	<ul style="list-style-type: none"> <li>• Not suitable for infants under 12 months.</li> </ul>
Hydrocortisone (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> <li>• CAUTION - do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Hydrocortisone (Entry 2 of 2)	In preparations for topical rectal use	<ul style="list-style-type: none"> <li>• CAUTION - do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) (Entry 1 of 2)	In Schedule 5 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li>• <i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>Avoid contact with eyes</li> <li>Avoid contact with skin.</li> </ul> </li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) (Entry 2 of 2)	In Schedule 6 or Schedule 7 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Highly corrosive Contact with eyes even for short periods can cause blindness Causes severe burns, which are not likely to be immediately painful or visible Avoid contact with eyes Avoid contact with skin Wear protective gloves when mixing or using Avoid breathing [dust/vapour/spray mist] Obtain a supply of calcium gluconate gel.</li> </ul>
Hydrogen peroxide (Entry 1 of 3)	In concentrations of more than 3 per cent up to 10 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Irritant Avoid contact with eyes.</li> </ul> <ul style="list-style-type: none"> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Hydrogen peroxide (Entry 2 of 3)	In concentrations of more than 10 per cent up to 20 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Irritant Attacks eyes - protect eyes when using.</li> </ul>
Hydrogen peroxide (Entry 3 of 3)	In concentrations of more than 20 per cent.	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Corrosive Attacks eyes - protect eyes when using Avoid contact with skin.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydrolysed milk protein – alpha caseozepine enriched	In listed medicines for oral ingestion.	<ul style="list-style-type: none"> <li>• Derived from cow’s milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice</li> </ul>
Hydroquinone	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>• WARNING - If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately.</li> <li>• Do not use on children.</li> <li>• Do not use near the eyes.</li> <li>• Mild irritation may occur; stop use if it becomes severe.</li> <li>• If fading is not evident in three months, seek doctor’s advice.</li> <li>• Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.</li> </ul>
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> (Entry 1 of 3)	Where the MRDD contains MORE than 10 milligrams and the product IS promoted or marketed as a laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• Drink plenty of water.</li> <li>• Prolonged use may cause serious bowel problems.</li> <li>• Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> <i>(Entry 2 of 3)</i>	Where the MRDD contains MORE than 10 milligrams and the product IS NOT promoted or marketed as a laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• This product may have a laxative effect.</li> <li>• Prolonged use may cause serious bowel problems.</li> <li>• Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.</li> <li>• This product contains <i>[insert name of the herb(s) or the chemical component(s)]</i>.</li> </ul>
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> <i>(Entry 3 of 3)</i>	Where the MRDD contains 10 milligrams OR LESS and the product IS promoted or marketed as laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• Drink plenty of water.</li> <li>• Prolonged use may cause serious bowel problems.</li> </ul>
8-Hydroxyquinoline (including salts and derivatives)	In preparations for internal use	<ul style="list-style-type: none"> <li>• Do not take for periods longer than four weeks except on medical advice.</li> </ul>
Hyoscine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>•</li> </ul>
Hyoscyamine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Hyoscyamus niger</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>•</li> </ul>
<i>Hypericum perforatum</i>	In listed medicines for oral use	<ul style="list-style-type: none"> <li>• St John's Wort affects the way many prescription medicines work, including oral contraceptives.</li> <li>• Consult your doctor.</li> </ul>
<p>Ibuprofen (Entry 1 of 6)</p> <p><i>NB: entry amended in Schedule 2</i></p>	In preparations for oral use when indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Ibuprofen (Entry 2 of 6)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use and:</p> <p>a. NOT indicated exclusively for the treatment of dysmenorrhoea; and</p> <p>b. NOT indicated for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you are aged 65 years or over.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Ibuprofen (Entry 3 of 6)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>When included in a schedule to the SUSMP for oral use, and the preparation is:</p> <p>a. NOT indicated exclusively for the treatment of dysmenorrhoea; and</p> <p>b. NOT indicated for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Ibuprofen (Entry 4 of 6)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use and:</p> <p>a. the preparation includes indications for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you are aged 65 years or over.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Ibuprofen (Entry 5 of 6)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>When included in a schedule to the SUSMP for oral use, and:</p> <p>a. the preparation includes indications for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>
<p>Ibuprofen (Entry 6 of 6)</p>	<p>In preparations for dermal use</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Indomethacin	In preparations for external use	<ul style="list-style-type: none"> <li>Do not use [this product/<i>insert name of product</i>] if you are allergic to indomethacin or other anti-inflammatory medicines.</li> <li>If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.</li> </ul>
Iodine (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> <li>If skin irritation or rash occurs, discontinue use immediately.</li> </ul>
Iodine (Entry 2 of 2)	In preparations for internal use containing 300 micrograms or more of iodine per recommended daily dose	<ul style="list-style-type: none"> <li>CAUTION - Total iodine intake may exceed recommended level when taking this preparation.</li> <li>WARNING - Contains iodine - do not take when pregnant except on physician's advice.</li> </ul>
Ipecacuanha (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>Do not give to children under 12 years of age.</li> </ul>
Ipecacuanha (Entry 2 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Ipratropium bromide	In metered aerosols	<ul style="list-style-type: none"> <li>This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Iron compounds	In listed medicines for internal use, EXCEPT for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims	<ul style="list-style-type: none"> <li>• Not for the treatment of iron deficiency.</li> </ul>
Ketoprofen <i>(Entry 1 of 4)</i>  <i>NB: entry amended in Schedule 2</i>	In preparations for oral use indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen <i>(Entry 2 of 4)</i>  <i>NB: entry amended            in Schedule 2</i>	When the preparation is for oral use and: a. NOT indicated exclusively for the treatment of dysmenorrhoea; and b. NOT indicated for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen <i>(Entry 3 of 4)</i>  <i>NB: entry amended            in Schedule 2</i>	When the preparation is for oral use and includes indications for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> </ul>
Ketoprofen <i>(Entry 4 of 4)</i>	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ketoprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.</li> </ul>
<i>Kunzea ambigua</i> <i>(Entry 1 of 2)</i>	In listed medicines when the preparation is "essential oil"	<ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Keep out of reach of children.</li> <li>• Not to be applied undiluted to the skin except on the advice of a healthcare practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Kunzea ambigua</i> (Entry 2 of 2)	In listed medicines when the preparation is other than “essential oil”	<ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Keep out of reach of children.</li> </ul>
Lactic acid (See Alpha hydroxy acids)	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area</li> <li>• Not recommended for use on children and infants</li> </ul>
Lactoferrin – bovine	In listed medicines	<ul style="list-style-type: none"> <li>• Derived from cow’s milk.</li> </ul>
Lansoprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
<i>Larrea tridentata</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Warning: Chaparral may harm the liver in some people.</li> <li>• Use only under the supervision of a healthcare professional.</li> </ul>
Lemon oil	For the purpose of exclusion from the schedules of the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Leptospermum scoparium</i> oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. in preparations containing more than 25 per cent of <i>Leptospermum scoparium</i> oil; and</p> <p>b. packed in containers having:</p> <p>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</p> <p>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</p>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Levocabastine (Entry 1 of 2)	In eye or nasal preparations containing 0.5 milligrams/millilitre or less of levocabastine	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> </ul>
Levocabastine (Entry 2 of 2)	In eye or nasal preparations containing MORE THAN 0.5 milligrams per millilitre of levocabastine.	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Levocetirizine (Entry 1 of 2)	In preparations for oral use labelled for use in adults	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Levocetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• This medication may cause drowsiness.</li> </ul>
Lignocaine (Entry 1 of 3)	In dermal preparations containing MORE THAN 2 per cent of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Lignocaine (Entry 2 of 3)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Lignocaine (Entry 3 of 3)	In lozenges	<ul style="list-style-type: none"> <li>• Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth.</li> <li>• Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.</li> </ul>
Lime oil	For the purpose of exclusion from the schedules of the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Lindane	In preparations for external use	<ul style="list-style-type: none"> <li>• Do not use on broken skin.</li> <li>• Ask your doctor or pharmacist before use.</li> <li>• This preparation should be used with caution on infants, small children and pregnant or breastfeeding women.</li> </ul>
Loperamide hydrochloride	In medicines for oral use	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> <li>• Do not give to children under 12 years of age.</li> <li>• Drink plenty of fluids as fluid and electrolyte depletion may occur with diarrhoea. If dehydration is suspected seek medical attention.</li> <li>• Do not take if you have a medical condition where constipation should be avoided.</li> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing condition affecting the bowel.</li> </ul>
Loratadine	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Marjoram oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations containing more than 50 per cent of marjoram oil; and</li> <li>b. packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Mefenamic acid  <i>NB: entry amended in Schedule 2</i>	When indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to mefenamic acid or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing mefenamic acid, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Melaleuca oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. in preparations containing more than 25 per cent of melaleuca oil; and</p> <p>b. when packed in containers having:</p> <p>i. a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</p> <p>ii. a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</p>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Methoxamine <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists consult your doctor or pharmacist.</li> </ul>
Miconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if problem returns.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> </ul>
Naphazoline <i>(Entry 1 of 2)</i> <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists consult your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naphazoline (Entry 2 of 2)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Naproxen (Entry 1 of 3)  NB: entry amended in Schedule 2	When indicated for oral use exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Naproxen (Entry 2 of 3)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>In preparations for oral use that are:</p> <p>a. NOT indicated exclusively for the treatment of dysmenorrhoea; and</p> <p>b. NOT indicated for use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<p>Naproxen (Entry 3 of 3)</p> <p><i>NB: entry amended in Schedule 2</i></p>	<p>When the preparation includes indications for oral use in children under 12 years of age</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> </ul>
<p>Nasal decongestant preparations, including:</p> <ul style="list-style-type: none"> <li>• Methoxamine</li> <li>• Naphazoline</li> <li>• Oxymetazoline</li> <li>• Phenylephrine</li> <li>• Tetrahydrozoline</li> <li>• Tramazoline</li> <li>• Tymazoline</li> <li>• Xylometazoline</li> </ul> <p><i>NB: entry amended in Schedule 2</i></p>	<p>When in nasal decongestant preparations for topical use</p>	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Nizatidine  <i>NB: entry amended in Schedule 2</i>	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> </ul>
Nutmeg oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ol style="list-style-type: none"> <li>a. in preparations containing more than 50 per cent of nutmeg oil; and</li> <li>b. packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Nystatin	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• If getting better, keep using for [<i>insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Omega-3 fish oil phytosterol esters	When in listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Not suitable for use by pregnant or lactating women.</li> <li>• There is no benefit from taking more than 3 g per day of phytosterols from all sources.</li> </ul>
Omeprazole	In preparations for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Orange oil (bitter)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> <li>Application to skin may increase sensitivity to sunlight.</li> </ul>
Oxymetazoline (Entry 1 of 4)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> </ul>
Oxymetazoline (Entry 2 of 4) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Oxymetazoline (Entry 3 of 4)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not give to children under 12 years of age.</li> </ul>
Oxymetazoline (Entry 4 of 4)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pantoprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Paracetamol (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> <li>• Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor.</li> <li>• Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.</li> <li>• If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.</li> <li>• Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.</li> </ul>
Paracetamol (Entry 2 of 2)	In Schedule 2 or 3 to the SUSMP	<ul style="list-style-type: none"> <li>• <ul style="list-style-type: none"> <li>- Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor.</li> </ul> </li> <li><i>and / or</i></li> <li>- Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.</li> <li>• If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.</li> <li>• Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.</li> </ul>
<i>Paullinia cupana</i>	In listed medicines	<ul style="list-style-type: none"> <li>• The goods contain caffeine.</li> <li>• Each [insert name of dosage unit] contains [insert quantity] of caffeine.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pennyroyal oil	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>a. in preparations containing more than 4 per cent of d-pulegone; and</li> <li>b. when packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Pentoxyverine <i>(Entry 1 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Pentoxyverine <i>(Entry 2 of 2)</i>  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Permanganates <i>(see also Potassium permanganate)</i>	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Corrosive Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>• This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>• This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Pheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Pheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Phenol and any other homologue of phenol	When included in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes Avoid contact with skin.</li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Phenylalanine	In listed medicines for oral or sublingual administration, the MRDD of which contains more than 500 milligrams of phenylalanine	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
Phenylephrine (Entry 1 of 7)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> </ul>
Phenylephrine (Entry 2 of 7) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Phenylephrine (Entry 3 of 7)	In oral preparations that are NOT indicated for cough, cold or flu	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> </ul>
Phenylephrine (Entry 4 of 7)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> <li>• Do not give to children under 12 years of age.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Phenylephrine (Entry 5 of 7)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Phenylephrine Entry 6 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu, which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Phenylephrine (Entry 7 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children under 'x' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pholcodine (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu, and the preparation does not include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>Do not give to children under 12 years of age.</li> </ul>
Pholcodine (Entry 2 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
<i>Piper methysticum</i> (Entry 1 of 2)	In listed medicines for oral use containing more than 25 mg of kavalactones per dose	<ul style="list-style-type: none"> <li>Not recommended for use by pregnant or lactating women.</li> <li>WARNING: Not for prolonged use.</li> <li>If symptoms persist, seek advice from a health care practitioner.</li> <li>May harm the liver.</li> </ul>
<i>Piper methysticum</i> (Entry 2 of 2)	For the purpose of exclusion from the schedules to the SUSMP in medicines for oral use	<ul style="list-style-type: none"> <li>Not recommended for use by pregnant or lactating women</li> <li>WARNING: Not for prolonged use</li> <li>If symptoms persist, seek advice from a health care practitioner.</li> <li>May harm the liver.</li> </ul>
Podophyllin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> <li>WARNING - Do not use on face or on anal or genital areas except on doctor's advice.</li> </ul>
Podophyllin (Entry 1 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> <li>WARNING - Do not use on face or on anal or genital areas.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Podophyllotoxin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas except on doctor's advice.</li> </ul>
Podophyllotoxin (Entry 2 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas.</li> </ul>
Pollen	When the ingredient is collected by bees and included in listed medicines (including as an excipient).	<ul style="list-style-type: none"> <li>• This product contains pollen which can cause severe allergic reactions.</li> </ul>
Potassium chloride (Entry 1 of 2)	In listed medicines for oral rehydration therapy exclusively for adults	<ul style="list-style-type: none"> <li>• Keep out of reach of children.</li> <li>• Contains [<i>amount of potassium</i>] potassium.</li> <li>• If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> <li>• Use only as directed.</li> <li>• If diarrhoea persists, seek medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)										
Potassium chloride (Entry 2 of 2)	In listed medicines for oral rehydration therapy and indicated for use in children	<ul style="list-style-type: none"> <li>• Keep out of reach of children.</li> <li>• Contains [<i>amount of potassium</i>] potassium.</li> <li>• If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> <li>• Use only as directed.</li> <li>• If diarrhoea persists, seek medical advice.</li> <li>• [<i>include the following additional directions in the 'Directions for Use'</i>]:</li> </ul> <table border="1"> <thead> <tr> <th>Age of child</th> <th>Additional Directions</th> </tr> </thead> <tbody> <tr> <td>Under 6 months</td> <td>Medical advice should be sought if diarrhoea persists for more than 6 hours</td> </tr> <tr> <td>Under 3 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 12 hours</td> </tr> <tr> <td>3 – 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 24 hours</td> </tr> <tr> <td>Over 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 48 hours</td> </tr> </tbody> </table>	Age of child	Additional Directions	Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours	Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours	3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours	Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours
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Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours											
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3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours											
Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours											
Potassium hydroxide (Entry 1 of 3)	When included in a schedule to the SUSMP, in preparations containing 0.5 per cent OR LESS of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Irritant</li> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Wash hands after use.</li> </ul> </li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>										

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Potassium hydroxide (Entry 2 of 3)	When included in a schedule to the SUSMP, in solid preparations containing MORE THAN 0.5 per cent of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using</li> <li>Do not mix with hot water.</li> </ul> </li> </ul>
Potassium hydroxide (Entry 3 of 3)	When included in a schedule to the SUSMP, in liquid preparations containing MORE THAN 0.5 per cent of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using.</li> </ul> </li> </ul>
Potassium permanganate	In Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.</li> </ul> </li> </ul>
Povidone-iodine	In preparations for dermal use	<ul style="list-style-type: none"> <li>• If skin irritation or rash occurs, discontinue use immediately.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Promethazine (Entry 1 of 4)	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Promethazine (Entry 2 of 4)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Promethazine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Promethazine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Propolis (Entry 1 of 2)	In listed medicines for internal use	<ul style="list-style-type: none"> <li>WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use.</li> </ul>
Propolis (Entry 2 of 2)	In listed medicines for external use	<ul style="list-style-type: none"> <li>WARNING: Propolis may cause skin irritation. Test before use.</li> </ul>
Proton pump inhibitors including: <ul style="list-style-type: none"> <li>Lansoprazole</li> <li>Omeprazole</li> <li>Pantoprazole</li> <li>Rabeprazole</li> </ul>	In medicines for oral use	<ul style="list-style-type: none"> <li>CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Pseudoephedrine (Entry 1 of 3)	When the preparation is NOT indicated for use for cough, cold or flu	<ul style="list-style-type: none"> <li>See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>[This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> </ul>
Pseudoephedrine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>[This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> <li>Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pseudoephedrine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Psyllium	In medicines for oral ingestion which include dosage instructions for children	<ul style="list-style-type: none"> <li>• Should only be used for children on medical advice.</li> </ul>
Pyrethrins	When used as an excipient in listed medicines for topical use	<ul style="list-style-type: none"> <li>• This product contains pyrethrins [<i>insert quantity</i>]</li> </ul>
Pyridoxal (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>• WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</li> </ul>
Pyridoxal (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>• WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>• WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</li> </ul>
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>• WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B.</li> </ul>
Pyrithione zinc	In preparations for external use for treatment of the scalp	<i>either</i> <ul style="list-style-type: none"> <li>• Keep out of eyes.</li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>• If in eyes, rinse well with water.</li> </ul>
Rabeprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Ranitidine  <i>NB: entry amended in Schedule 2</i>	Medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> </ul>
Royal jelly	In listed medicines	<ul style="list-style-type: none"> <li>• Not suitable for use by children.</li> <li>• Not to be taken by asthma and allergy sufferers. <a href="#">[k]</a> <a href="#">[l]</a></li> <li>• This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy sufferers.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Safrole	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> </ul>
Sage oil	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>a. in preparations containing more than 4 per cent of thujone; and</li> <li>b. packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Salbutamol	In metered aerosols or in dry powder formulations	<ul style="list-style-type: none"> <li>• This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>
Sassafras oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> </ul>
Selenium yeast – high	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Selenocysteine	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Selenomethionine	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Senega (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Senega (Entry 2 of 2)  <i>NB: entry amended in Schedule 2</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Shark cartilage	In listed medicines	<ul style="list-style-type: none"> <li>• Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)										
Silver <i>(see also Silver salts)</i>	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>in chewing gum containing 5 milligrams or less of silver per dosage unit; or</li> <li>in solutions for oral use containing 0.3 per cent or less of silver</li> </ol>	<ul style="list-style-type: none"> <li>Overuse may stain skin or mouth.</li> </ul>										
Silver salts <i>(see also Silver)</i>	In smoking deterrents.	<ul style="list-style-type: none"> <li>WARNING - Overuse may stain the skin or mouth.</li> </ul>										
Sodium bicarbonate <i>(Entry 1 of 2)</i>	In listed medicines for oral rehydration therapy exclusively for adults	<ul style="list-style-type: none"> <li>Use only as directed.</li> <li>If diarrhoea persists, seek medical advice.</li> </ul>										
Sodium bicarbonate <i>(Entry 2 of 2)</i>	In listed medicines for oral rehydration therapy that are indicated for use in children	<ul style="list-style-type: none"> <li>Use only as directed.</li> <li>If diarrhoea persists, seek medical advice.</li> <li><i>[include the following additional directions in the 'Directions for Use']:</i></li> </ul> <table border="1"> <thead> <tr> <th>Age of child</th> <th>Additional Directions</th> </tr> </thead> <tbody> <tr> <td>Under 6 months</td> <td>Medical advice should be sought if diarrhoea persists for more than 6 hours</td> </tr> <tr> <td>Under 3 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 12 hours</td> </tr> <tr> <td>3 – 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 24 hours</td> </tr> <tr> <td>Over 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 48 hours</td> </tr> </tbody> </table>	Age of child	Additional Directions	Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours	Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours	3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours	Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours
Age of child	Additional Directions											
Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours											
Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours											
3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours											
Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours											
Sodium fluoride <i>(see also Fluorides)</i>	In preparations for ingestion when in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>Use of this product is not necessary in areas supplied with fluoridated water.</li> </ul>										

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Sodium hydroxide (Entry 1 of 3)	When included in a schedule to the SUSMP, in preparations containing 0.5 per cent or less of sodium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Irritant</li> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Wash hands after use.</li> </ul> </li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Sodium hydroxide (Entry 2 of 3)	When included in a schedule to the SUSMP, in solid preparations containing more than 0.5 per cent of sodium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using</li> <li>Do not mix with hot water.</li> </ul> </li> </ul>
Sodium hydroxide (Entry 3 of 3)	When included in a schedule to the SUSMP, in liquid preparations containing more than 0.5 per cent of sodium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using.</li> </ul> </li> </ul>
Sodium selenate	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Sodium selenite	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Sodium sulfate	In listed medicines	<ul style="list-style-type: none"> <li>• This preparation may have a laxative effect.</li> </ul>
Squid oil	In listed medicines	<ul style="list-style-type: none"> <li>• DERIVED FROM SEAFOOD</li> </ul>
(S)-S-Adenosylmethionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>
Star anise oil	For the purpose of exclusion from the schedules to the SUSMP when: <ol style="list-style-type: none"> <li>in preparations containing more than 50 per cent of star anise oil; and</li> <li>packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ol>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Sugar cane wax alcohols	In listed medicines	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or lactating women.</li> </ul>
<i>Symphytum</i> spp	In Schedule 5 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Do not use on broken skin</li> <li>Do not use under occlusive dressing.</li> </ul> </li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Terbutaline	In metered aerosols	<ul style="list-style-type: none"> <li>• This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>
Tetrahydrozoline (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> </ul>
Tetrahydrozoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Thyme oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>a. in preparations containing more than 50 per cent of thyme oil; and</li> <li>b. packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Tioconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Do not use if you are pregnant.</li> <li>• See a doctor before use if you are diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Tramazoline (entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Tramazoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Triamcinolone	In topical preparations for the treatment of mouth ulcers	<p><i>either</i></p> <ul style="list-style-type: none"> <li>• See a [doctor / doctor or dentist] if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>• If symptoms persist beyond 5 days consult a [doctor / doctor or dentist].</li> </ul>
Tripolidine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Tripolidine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul> <p><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></p> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Triprolidine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Tymazoline (Entry 1 of 2)  <i>NB: entry amended in Schedule 2</i>	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> </ul>
Tymazoline (Entry 2 of 2) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Ubidecarenone	In listed medicines	<ul style="list-style-type: none"> <li>Not to be taken, if on warfarin therapy, without medical advice.</li> </ul>
Ubiquinol-10	In listed medicines	<ul style="list-style-type: none"> <li>Not to be taken, if on warfarin therapy, without medical advice.</li> </ul>
Vasoconstrictor eye drops including: <ul style="list-style-type: none"> <li>Naphazoline</li> <li>Oxymetazoline</li> <li>Phenylephrine</li> <li>Tetrahydrozoline</li> <li>Tramazoline</li> <li>Tymazoline</li> <li>Xylometazoline</li> </ul>	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Vegetable oil phytosterol esters	In preparations for oral ingestion	<ul style="list-style-type: none"> <li>Not suitable for use by pregnant or lactating women.</li> <li>There is no benefit from taking more than 3 g/ day of phytosterols from all sources.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Vitamin A (See also Vitamins)	In medicines for oral use that are labelled to be used by females of childbearing age containing MORE THAN: a. 33 micrograms retinol equivalents of vitamin A per dosage unit of a divided preparation; or b. 33 micrograms retinol equivalents of vitamin A per gram of an undivided preparation	<ul style="list-style-type: none"> <li>• <b>The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.</b></li> <li>• <b>WARNING – When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.</b> <a href="#">[c]</a></li> <li>• <b>If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.</b> <a href="#">[c]</a></li> </ul>
Vitamin B6 • pyridoxal • pyridoxine (Entry 1 of 2) (See also Vitamins)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> <li>• <b>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</b></li> </ul>
Vitamin B6 • pyridoxal • pyridoxine (Entry 2 of 2) (See also Vitamins)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> <li>• <b>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.</b></li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Vitamins (see also: Pyridoxal, Pyridoxine, Vitamin A, Vitamin B6)	In listed medicines	<i>either</i> <ul style="list-style-type: none"> <li>Vitamins can only be of assistance if the dietary vitamin intake is inadequate.</li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>Vitamin supplements should not replace a balanced diet.</li> </ul>
Wheat dextrin	When used as an excipient in listed medicines for oral use	<ul style="list-style-type: none"> <li>Contains gluten.</li> </ul>
Xylometazoline (Entry 1 of 4)  NB: entry amended in Schedule 2	When in nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> </ul>
Xylometazoline (Entry 2 of 4) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Xylometazoline (Entry 3 of 4)  NB: entry amended in Schedule 2	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not give to children under 12 years of age.</li> </ul>
Xylometazoline (Entry 4 of 4)  NB: entry amended in Schedule 2	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not give to children under 'x' years of age.</li> <li><i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Yeast – high selenium	In listed medicines	<ul style="list-style-type: none"> <li>This product contains selenium which is toxic in high doses.</li> <li>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Zinc chloride	In a schedule to the SUSMP	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li><b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin.</li> </ul> </li> </ul>
Zinc compounds	In preparations for internal use with a recommended daily dose of more than 25 milligrams of zinc	<p><i>either</i></p> <ul style="list-style-type: none"> <li>WARNING - This medication may be dangerous when used in large amounts or for a long period.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>WARNING – Contains zinc, which may be dangerous when used in large amounts or for a long period.</li> </ul>
Zinc sulfate	In Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li><b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin.</li> </ul> </li> </ul>
<i>Zingiber officinale</i>	In listed medicines: <ul style="list-style-type: none"> <li>a. when the extraction ratio is 25:1 or higher; and</li> <li>b. when the equivalent dry weight per dosage unit is 2 grams or higher</li> </ul>	<ul style="list-style-type: none"> <li>Individuals taking anticoagulants should seek medical advice before taking this product.</li> <li>Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product.</li> </ul>



## **Schedule 2**

# **Required Advisory Statements for Medicine Labels No. 3**

## **(section 5)**

## Schedule 2

### Required Advisory Statements for Medicine Labels No. 3

#### Advisory statements

Where a medicine:

- 1) includes a substance described in Column 1 of *Table 1: Medicines to Which Advisory Statements Apply* ('the table'), below; and
- 2) meets the condition(s) described in Column 2 of the table;

the statement(s) set out in Column 3 of the table must be contained on the labels of the medicine in accordance with the Labelling Order, in a manner that is compliant with any applicable presentation requirement(s) set out below (the requirements are indicated in the table by the presence of the applicable alphabetical in square brackets, next to the statement or, in the case of a requirement to use upper case and/or bold face, by use of upper case and/or bold face letters in the statement itself).

Unless otherwise specified, the requirements apply only if the substance is included in the medicine as an active ingredient.

#### Permitted variation and combination of statements

The wording of the statements specified in this document may be varied provided that the intent is not changed.

Where more than one statement is required, they may be combined to form simple sentences where appropriate, provided that the intent is not changed and that any additional requirements are also met.

#### Additional presentation requirements for some advisory statements

In some cases, additional requirements apply to advisory statements, such as font, letter size etc. Where such additional requirements apply, they are indicated in Column 3 of Table 1 below either by a letter in square brackets (e.g. [c]) or, in the case of a requirement to use upper case and/or bold face, by use of upper case and/or bold face letters in the statement itself. The meaning of the letters is set out below:

[c]: Statement(s) must be included at the beginning of the directions for use on the label.

[f]: Statement(s) must be included on the label written:

- (i) on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN"; and
- (ii) in bold-face sanserif capital letters of uniform thickness; and
- (iii) in letters as least four tenths the height of the letters used for the signal heading; and
- (iv) with nothing else besides the statement written on the same line.

[g]: Statement(s), written in sanserif capital letters, must be included on the main label or as part of the directions for use.

[k]: Statement(s) must be printed in type of 3 mm height or larger.

[l]: Statement(s) must be printed on the front of the goods.



**Table 1: Medicines to which advisory statements apply**

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Acetone	In concentrations greater than 75 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Avoid breathing [vapour/spray mist]</li> </ul> </li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
<i>Actaea racemosa</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Warning: In very rare cases, Black cohosh has been associated with liver failure.</li> <li>• If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.</li> </ul>
Activated charcoal	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing activated charcoal should be used with caution in children since it may interfere with the absorption of nutrients.</li> <li>• This substance may interact with other medicines.</li> <li>• Activated charcoal is not recommended for long-term use.</li> </ul>
Ademetionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>
(S)-S-Adenosylmethionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Alclometasone	When included in Schedule 3 to the SUSMP	<ul style="list-style-type: none"> <li>• CAUTION - Do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Alpha casozepine enriched hydrolysed milk protein	In listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Alpha hydroxy acids, including: <ul style="list-style-type: none"> <li>• citric acid and other fruit acids</li> <li>• glycollic acid</li> <li>• lactic acid</li> </ul>	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>• Not recommended for use on children and infants.</li> </ul>
Amethocaine (Entry 1 of 2)	When included in Schedule 2 to the SUSMP and for dermal use	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Amethocaine (Entry 2 of 2)	For the purpose of exclusion from the schedules of the SUSMP when in dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ammonia and ammonium salts, including <ul style="list-style-type: none"> <li>• ammonium chloride</li> <li>• ammonium bicarbonate</li> <li>• ammonium carbonate</li> </ul> <i>(Entry 1 of 2)</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Ammonia and ammonium salts, including <ul style="list-style-type: none"> <li>• ammonium chloride</li> <li>• ammonium bicarbonate</li> <li>• ammonium carbonate</li> </ul> <i>(Entry 2 of 2)</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Anise oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in preparations containing more than 50 per cent of anise oil; and</li> <li>• packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines (Entry 1 of 5)	When included in a schedule to the SUSMP and NOT separately specified in the table and NOT: <ul style="list-style-type: none"> <li>• dermal, ocular or paediatric preparations; or</li> <li>• oral preparations of desloratadine, loratadine or fexofenadine; or</li> <li>• nasal preparations of azelastine</li> </ul>	<p><i>either</i></p> <ul style="list-style-type: none"> <li>• This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>• This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul>
Antihistamines (Entry 2 of 5)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Antihistamines (Entry 3 of 5)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul> <p><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></p> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines (Entry 4 of 5)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Antihistamines (Entry 5 of 5), including: -Diphenhydramine -Doxylamine -Promethazine	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Arginine	In listed medicines	<ul style="list-style-type: none"> <li>• This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa, vagina or rectum.</li> </ul>
Aspartame	When for oral ingestion and included in medicines as an active or excipient ingredient	<ul style="list-style-type: none"> <li>• Phenylketonurics are warned that this product contains aspartame (phenylalanine).</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 1 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains MORE than 100 milligrams of aspirin; and</p> <p>b. the preparation is NOT indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 2 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains MORE than 100 milligrams of aspirin; and</p> <p>b. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 3 of 7)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <p>a. each dosage unit contains 100 milligrams OR LESS of aspirin; and</p> <p>b. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation</p>	<ul style="list-style-type: none"> <li>• For use under medical supervision only</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 4 of 7)	When included in a schedule to the SUSMP and: a. the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or b. in sustained release preparations containing 650 milligrams or more of aspirin	<ul style="list-style-type: none"> <li>• For use under medical supervision only.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 5 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. the preparation IS indicated exclusively for treatment of dysmenorrhoea; and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. NOT in combination with other therapeutically active substances (other than effervescent agents)</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 6 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. in combination with other therapeutically active substances (other than effervescent agents); and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. NOT indicated:</p> <p>i. for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or</p> <p>ii. exclusively for treatment of dysmenorrhoea</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 7 of 7)	<p>When included in a schedule to the SUSMP and:</p> <p>a. NOT in combination with other therapeutically active substances (other than effervescent agents); and</p> <p>b. NOT in sustained release preparations containing 650 milligrams or more of aspirin; and</p> <p>c. NOT indicated:</p> <p>i. for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or</p> <p>ii. exclusively for treatment of dysmenorrhoea</p>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to aspirin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] for more than a few days at a time.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children under 12 years of age.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• See a doctor before taking [this product/<i>insert name of product</i>] for thinning the blood or for your heart.</li> </ul>
Atropa belladonna	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Atropine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
<i>Azadirachta indica</i> (neem) (Entry 1 of 2)	When: <ul style="list-style-type: none"> <li>• included in listed medicines; or</li> <li>• for the purpose of exclusion from the schedules to the SUSMP when in preparations for dermal use and in a container fitted with a child resistant closure</li> </ul>	<ul style="list-style-type: none"> <li>• Not to be taken.</li> <li>• Keep out of reach of children.</li> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
<i>Azadirachta indica</i> including its extracts and derivatives (Entry 2 of 2)	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
Azelastine	In preparations for topical ophthalmic or nasal administration	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
<i>Backhousia citriodora</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Not recommended for use by children aged 12 years or under.</li> <li>• Not recommended for use by pregnant or lactating women.</li> <li>• If skin irritation occurs, discontinue use.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Basil oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations or oils containing more than 5 per cent of methyl chavicol; and</li> <li>• packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Bay oil	<p>For the purpose of exclusion from the schedules to the SUSMP when</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of bay oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>- a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>- a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN</li> </ul>
Benzocaine (Entry 1 of 3)	<p>In dermal preparations containing MORE than 2 per cent of total local anaesthetic substances</p>	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Benzocaine (Entry 2 of 3)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Benzocaine (Entry 3 of 3)	In lozenges	<ul style="list-style-type: none"> <li>• Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth.</li> <li>• Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.</li> </ul>
Benzoyl peroxide	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>• Keep from eyes, lips, mouth and sensitive areas of the neck.</li> <li>• If excessive swelling, irritation, redness or peeling occurs, discontinue use.</li> <li>• If these persist, consult a physician.</li> <li>• Avoid excessive exposure to sunlight and other sources of ultra violet light.</li> </ul>
Benzydamine	In preparations for topical use or dermal use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to benzydamine or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> </ul>
Bergamot oil	For the purpose of exclusion from the schedules to the SUSMP; or when included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>
Bovine colostrum powder	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing bovine colostrum powder contain lactose and cow's milk proteins.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Bovine lactoferrin	In listed medicines	<ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> </ul>
Bovine whey IG-rich fraction	In listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Bromhexine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Bromhexine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Brompheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• Do not give to children under 12 years of age.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Brompheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Brompheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Butoconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Do not use if you are pregnant.</li> <li>• See a doctor before use if you are diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [Insert number of days as per approved Product Information] days.</li> <li>• See a doctor if problem returns.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Caffeine (Entry 1 of 2)	<p>In listed medicines, except medicines containing less than 1 milligram of caffeine in the MRDD:</p> <ul style="list-style-type: none"> <li>• for oral or sublingual administration; and</li> <li>• the MRDD of which contains 10 milligrams OR LESS of caffeine or less; and</li> <li>• when the caffeine is from a herbal source</li> </ul>	<ul style="list-style-type: none"> <li>• The recommended dose of this medicine provides small amounts of caffeine.</li> </ul>
Caffeine (Entry 2 of 2)	<p>In listed medicines:</p> <ul style="list-style-type: none"> <li>• for oral or sublingual administration; and</li> <li>• the MRDD of which contains MORE THAN 10 milligrams of caffeine; and</li> <li>• when the caffeine is from a herbal source</li> </ul>	<ul style="list-style-type: none"> <li>• Contains [<i>amount of caffeine in milligrams</i>] mg of caffeine.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cajuput oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations or oils containing more than 25 per cent of cajuput oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Calcium sodium caseinate	In listed medicines	<p><i>either</i></p> <ul style="list-style-type: none"> <li>• Derived from cow's milk.</li> </ul> <p><i>or</i></p> <ul style="list-style-type: none"> <li>• Contains cow's milk protein.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Camphor <i>(Entry 1 of 3)</i>	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• included as a natural component in essential oils containing greater than 2.5 per cent of camphor but 10 per cent or less of camphor; and</li> <li>• packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> <li>• Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Camphor (Entry 2 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in essential oils when the camphor is present as a natural component of the oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>- a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>- a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> <li>• Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.</li> </ul>
Camphor (Entry 3 of 3)	<p>When:</p> <ul style="list-style-type: none"> <li>• included in a schedule to the SUSMP, and</li> <li>• not in block, ball or pellet form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.</li> </ul>	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Can be fatal to children if sucked or swallowed. Avoid contact with eyes.</li> </ul>
<i>Canarium indicum</i>	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains material derived from nuts.</li> </ul>
<i>Carthamus tinctorius</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cassia oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with skin.</li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>
Cetirizine (Entry 1 of 2)	In preparations for oral use that are NOT specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Cetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• This medication may cause drowsiness.</li> </ul>
Charcoal – activated	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing activated charcoal should be used with caution in children since it may interfere with the absorption of nutrients.</li> <li>• This substance may interact with other medicines.</li> <li>• Activated charcoal is not recommended for long term use.</li> </ul>
<i>Chelidonium majus</i>	When the preparation is for oral use.	<ul style="list-style-type: none"> <li>• Warning: Greater Celandine may harm the liver in some people.</li> <li>• Use only under the supervision of a healthcare professional.</li> </ul>
Chitosan (Entry 1 of 2)	In listed medicines, except in oral powder dosage form.	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> <li>• Chitosan should be taken at least one hour after any other medication as it may reduce the effect of other medication.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chitosan (Entry 2 of 2)	In listed medicines in oral powder dosage form.	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> <li>• Chitosan should be taken at least one hour after any other medication as it may reduce the effect of other medication.</li> <li>• Do not take powder alone. Mix with food or fluid.</li> </ul>
Chloramphenicol	In medicines for ophthalmic use	<ul style="list-style-type: none"> <li>• Contact lens wearers should not use this product except on the advice of a doctor or optometrist.</li> <li>• If your eye infection does not improve within 48 hours, seek immediate medical advice.</li> <li>• Do not use in children under 2 years of age except on medical advice.</li> </ul>
Chlorhexidine (Entry 1 of 2)	In topical products, including preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> <li>• Avoid contact with eyes.</li> <li>• If in eyes, rinse well with water.</li> <li>• WARNING – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs.</li> </ul>
Chlorhexidine (Entry 2 of 2)	In topical products OTHER THAN preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> <li>• Avoid contact with eyes.</li> <li>• If in eyes, rinse well with water.</li> <li>• Mild irritation may occur; stop use if it becomes severe.</li> </ul>
Chlorpheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chlorpheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Chlorpheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Choline salicylate	In preparations for topical oral use.	<ul style="list-style-type: none"> <li>• Do not exceed the recommended dose. Excessive or prolonged use can be harmful.</li> </ul>
Chromates (including dichromates) of alkali metals or ammonia	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Avoid breathing [dust]/[vapour]/[ spray mist].</li> </ul> </li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cimetidine	In Schedule 3 to the SUSMP	<ul style="list-style-type: none"> <li>• Use only under medical supervision if you are taking other medicines.</li> <li>• CAUTION: This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks , consult a doctor.</li> </ul>
Cinchocaine (Entry 1 of 2)	In preparations for rectal use only	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Cinchocaine (Entry 2 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Cineole	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations or oils containing more than 25 per cent of cineole (other than rosemary oil or camphor oil); and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cinnamon bark oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with skin</li> </ul> </li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Cinnamon leaf oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of cinnamon leaf oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>- a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>- a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>KEEP OUT OF REACH OF CHILDREN.</b></li> <li>• <b>NOT TO BE TAKEN.</b></li> </ul>
Citric acid and other fruit acids <i>(See also Alpha hydroxy acids)</i>	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>• Not recommended for use on children and infants.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Clobetasone	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> <li>• CAUTION - Do not use for children under 12 years old unless a doctor has told you to.</li> </ul>
Clotrimazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Clove oil (Entry 1 of 2)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of clove oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>- a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>- a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Clove oil (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Coal tar	In preparations for topical use	<ul style="list-style-type: none"> <li>• Avoid contact with eyes.</li> <li>• If skin irritation occurs, discontinue use.</li> <li>• Do not use for prolonged periods except on the advice of a doctor or pharmacist.</li> </ul>
Codeine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Codeine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>- If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Colostrum powder – bovine	In listed medicines	<ul style="list-style-type: none"> <li>• Products containing bovine colostrum powder contain lactose and cow's milk proteins.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice.</li> </ul>
Concentrated omega-3-triglycerides - squid	In listed medicines	<ul style="list-style-type: none"> <li>• <b>DERIVED FROM SEAFOOD</b></li> </ul>
Creatine	In listed medicines	<ul style="list-style-type: none"> <li>• Seek professional advice before long term use.</li> </ul>
Creatine monohydrate	In listed medicines	<ul style="list-style-type: none"> <li>• Seek professional advice before long term use.</li> </ul>
Creatine phosphate	In listed medicines	<ul style="list-style-type: none"> <li>• Seek professional advice before long term use.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Datura spp</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
Desloratadine	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Dexchlorpheniramine <i>(Entry 1 of 3)</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Dexchlorpheniramine <i>(Entry 2 of 3)</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul> <p><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></p> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dexchlorpheniramine <i>(Entry 3 of 3)</i>	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Dextromethorphan <i>(Entry 1 of 2)</i>	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Dextromethorphan <i>(Entry 2 of 2)</i>	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>- If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Dibromopropamide	In medicines for ophthalmic use	<ul style="list-style-type: none"> <li>• Contact lens wearers should not use this product except on the advice of a doctor or optometrist.</li> <li>• If your eye infection does not improve within 48 hours, seek immediate medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac (Entry 1 of 4)	In preparations for oral use when indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac (Entry 2 of 4)	In preparations for oral use in adults and children aged 12 years and over, when NOT indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac (Entry 3 of 4)	In preparations indicated for oral use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> </ul>
Diclofenac (Entry 4 of 4)	When the preparation is for dermal use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.</li> </ul>
Diethyltoluamide (DEET)	All, including where present as an excipient	<ul style="list-style-type: none"> <li>• WARNING - May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dihydrocodeine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Dihydrocodeine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Diphenhydramine (Entry 1 of 4)	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Diphenhydramine (Entry 2 of 4)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• Do not give to children under 12 years of age.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diphenhydramine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Diphenhydramine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Diphenoxylate	In medicines for oral use	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Doxylamine (Entry 1 of 4)	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>
Doxylamine (Entry 2 of 4)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Doxylamine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>– Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Doxylamine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• either (if 'x' is 11)               <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10)               <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Econazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• See a doctor if no better after [Insert number of days as per approved Product Information] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Esomeprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Eucalyptus oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of eucalyptus oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Eugenol (Entry 1 of 2)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of eugenol; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Eugenol (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>
<i>Euphausia superba</i> oil (Krill oil)	In listed medicines	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- Contains crustacean shellfish.</li> <li><i>or</i></li> <li>- Derived from seafood.</li> </ul> </li> </ul>
<i>Fallopia multiflora</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Warning: <i>Fallopia multiflora</i> may harm the liver in some people.</li> <li>• Use under the supervision of a healthcare professional.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Famciclovir	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are taking other medicines regularly, consult your pharmacist or doctor before use.</li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you are allergic to famciclovir or penciclovir.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you have problems with your immune system.</li> <li>• Do not take [this product/<i>insert name of product</i>] if you have kidney problems, unless advised by a doctor.</li> <li>• If you have high blood pressure, heart problems, liver problems, diabetes or other medical conditions, consult your pharmacist or doctor before use.</li> <li>• If you have symptoms and signs of an infection other than your cold sore, consult your pharmacist or doctor before use.</li> </ul>
Famotidine	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks, consult a doctor.</li> </ul>
Fexofenadine	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Fluconazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> <li>• See a doctor before use if you are diabetic.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Fluorides (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in listed medicines for dental use (pastes, powders or gels for cleaning the teeth) containing more than 1,000 mg/kg of fluoride ion; or</li> <li>• in dental hygiene products (other than pastes, powders or gels for the cleaning of teeth) containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 milligrams total fluoride fitted with a child-resistant closure</li> </ul>	<ul style="list-style-type: none"> <li>• Do not swallow.</li> <li>• Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> </ul>
Fluorides (Entry 2 of 3)	When included in a schedule to the SUSMP except oral fluoride supplements	<ul style="list-style-type: none"> <li>• Do not swallow.</li> <li>• Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> </ul>
Fluorides (Entry 3 of 3)	In Schedule 2 to the SUSMP in oral preparations as fluoride supplements	<ul style="list-style-type: none"> <li>• Do not use if pregnant</li> <li>• Use of this product is not necessary in areas supplied with fluoridated water</li> <li>• Do not use except on the advice of a dentist</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Flurbiprofen (Entry 1 of 2)	In oral preparations that do NOT include indications for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to flurbiprofen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Flurbiprofen (Entry 2 of 2)	In oral preparations that include indications for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to flurbiprofen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> </ul>
Folic acid	In preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects	<ul style="list-style-type: none"> <li>• Do not exceed the stated dose except on medical advice.</li> <li>• If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice.</li> </ul>
Glucosamine hydrochloride	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>
Glucosamine sulfate	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>• Derived from seafood.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Glucosamine sulfate potassium chloride complex (Entry 1 of 2)	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>Derived from seafood.</li> </ul>
Glucosamine sulfate potassium chloride complex (Entry 2 of 2)	In listed medicines for oral use	<ul style="list-style-type: none"> <li>Keep out of reach of children.</li> <li>Contains [<i>amount of potassium</i>] potassium.</li> <li>If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> </ul>
Glucosamine sulfate sodium chloride complex	In listed medicines, when derived from a marine source	<ul style="list-style-type: none"> <li>Derived from seafood.</li> </ul>
Glycollic acid (See <i>Alpha hydroxy acids</i> )	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>This product may make your skin more sensitive to sunlight and other sources of UV light.</li> <li>Sun exposure should be limited by using a sunscreen and by wearing protective clothing.</li> <li>Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use.</li> <li>If you have sensitive skin, test this product on a small area of skin before applying it to a large area.</li> <li>Not recommended for use on children and infants.</li> </ul>
Guaifenesin (Guaiphenesin) (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>Do not give to children under 12 years of age.</li> <li>If [<i>coughing/symptoms</i>] persist(s), consult your doctor or pharmacist.</li> </ul>
Guaifenesin (Guaiphenesin) (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>If [<i>coughing/symptoms</i>] persist(s), consult your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hexachlorophane	In preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	<ul style="list-style-type: none"> <li>• For external washing only.</li> <li>• Rinse skin thoroughly after use.</li> </ul>
High selenium yeast	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Honey	In listed medicines	<ul style="list-style-type: none"> <li>• Not suitable for infants under 12 months.</li> </ul>
Hydrocortisone (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> <li>• CAUTION - do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use in the eyes.</li> <li>• Do not use for acne.</li> <li>• Do not use under waterproof bandages unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Hydrocortisone (Entry 2 of 2)	In preparations for topical rectal use	<ul style="list-style-type: none"> <li>• CAUTION - do not use for children under 2 years old unless a doctor has told you to.</li> <li>• Do not use for more than 7 days unless a doctor has told you to.</li> </ul>
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) (Entry 1 of 2)	In Schedule 5 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li>• <i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>Avoid contact with eyes</li> <li>Avoid contact with skin.</li> </ul> </li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) (Entry 2 of 2)	In Schedule 6 or Schedule 7 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING</b> [f]</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Highly corrosive Contact with eyes even for short periods can cause blindness Causes severe burns, which are not likely to be immediately painful or visible Avoid contact with eyes Avoid contact with skin Wear protective gloves when mixing or using Avoid breathing [dust/vapour/spray mist] Obtain a supply of calcium gluconate gel.</li> </ul>
Hydrogen peroxide (Entry 1 of 3)	In concentrations of more than 3 per cent up to 10 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Irritant Avoid contact with eyes.</li> </ul> <ul style="list-style-type: none"> <li>• <b>DO NOT SWALLOW.</b> [g]</li> </ul>
Hydrogen peroxide (Entry 2 of 3)	In concentrations of more than 10 per cent up to 20 per cent	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Irritant Attacks eyes - protect eyes when using.</li> </ul>
Hydrogen peroxide (Entry 3 of 3)	In concentrations of more than 20 per cent.	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b> Corrosive Attacks eyes - protect eyes when using Avoid contact with skin.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydrolysed milk protein – alpha caseozepine enriched	In listed medicines for oral ingestion.	<ul style="list-style-type: none"> <li>• Derived from cow’s milk.</li> <li>• This product is not suitable for use in children under the age of 12 months except on professional health advice</li> </ul>
Hydroquinone	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>• WARNING - If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately.</li> <li>• Do not use on children.</li> <li>• Do not use near the eyes.</li> <li>• Mild irritation may occur; stop use if it becomes severe.</li> <li>• If fading is not evident in three months, seek doctor’s advice.</li> <li>• Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.</li> </ul>
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> <i>(Entry 1 of 3)</i>	Where the MRDD contains MORE than 10 milligrams and the product IS promoted or marketed as a laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• Drink plenty of water.</li> <li>• Prolonged use may cause serious bowel problems.</li> <li>• Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.</li> </ul>
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> <i>(Entry 2 of 3)</i>	Where the MRDD contains MORE than 10 milligrams and the product IS NOT promoted or marketed as a laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• This product may have a laxative effect.</li> <li>• Prolonged use may cause serious bowel problems.</li> <li>• Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.</li> <li>• This product contains [<i>insert name of the herb(s) or the chemical component(s)</i>].</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> <li>• Aloe</li> <li>• Buckthorn</li> <li>• Cascara</li> <li>• Frangula</li> <li>• Rhubarb</li> <li>• Senna</li> </ul> (Entry 3 of 3)	Where the MRDD contains 10 milligrams OR LESS and the product IS promoted or marketed as laxative	<ul style="list-style-type: none"> <li>• Not recommended for use by children under 12 years of age.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• Drink plenty of water.</li> <li>• Prolonged use may cause serious bowel problems.</li> </ul>
8-Hydroxyquinoline (including salts and derivatives)	In preparations for internal use	<ul style="list-style-type: none"> <li>• Do not take for periods longer than four weeks except on medical advice.</li> </ul>
Hyoscine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
Hyoscyamine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist</li> </ul>
<i>Hyoscyamus niger</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> </ul>
<i>Hypericum perforatum</i>	In listed medicines for oral use	<ul style="list-style-type: none"> <li>• St John's Wort affects the way many prescription medicines work, including oral contraceptives.</li> <li>• Consult your doctor.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 1 of 6)	In preparations for oral use when indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 2 of 6)	<p>For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use and:</p> <ul style="list-style-type: none"> <li>• NOT indicated exclusively for the treatment of dysmenorrhoea; and</li> <li>• NOT indicated for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you are aged 65 years or over.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 3 of 6)	<p>When included in a schedule to the SUSMP for oral use, and the preparation is:</p> <ul style="list-style-type: none"> <li>• NOT indicated exclusively for the treatment of dysmenorrhoea; and</li> <li>• NOT indicated for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 4 of 6)	<p>For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use and:</p> <ul style="list-style-type: none"> <li>the preparation includes indications for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>Do not use if you have impaired kidney function.</li> <li>Do not use if you have heart failure.</li> <li>Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.</li> <li>Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you are aged 65 years or over.</li> <li>Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 5 of 6)	<p>When included in a schedule to the SUSMP for oral use, and:</p> <ul style="list-style-type: none"> <li>the preparation includes indications for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>Do not use if you have impaired kidney function.</li> <li>Do not use if you have heart failure.</li> <li>Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>
Ibuprofen (Entry 6 of 6)	In preparations for dermal use	<ul style="list-style-type: none"> <li>Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Indomethacin	In preparations for external use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to indomethacin or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.</li> </ul>
Iodine (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> <li>• If skin irritation or rash occurs, discontinue use immediately.</li> </ul>
Iodine (Entry 2 of 2)	In preparations for internal use containing 300 micrograms or more of iodine per recommended daily dose	<ul style="list-style-type: none"> <li>• CAUTION - Total iodine intake may exceed recommended level when taking this preparation.</li> <li>• WARNING - Contains iodine - do not take when pregnant except on physician's advice.</li> </ul>
Ipecacuanha (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Ipecacuanha (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>- If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Ipratropium bromide	In metered aerosols	<ul style="list-style-type: none"> <li>• This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Iron compounds	In listed medicines for internal use, EXCEPT for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims	<ul style="list-style-type: none"> <li>• Not for the treatment of iron deficiency.</li> </ul>
Ketoprofen (Entry 1 of 4)	In preparations for oral use indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen (Entry 2 of 4)	<p>When the preparation is for oral use and:</p> <ul style="list-style-type: none"> <li>• NOT indicated exclusively for the treatment of dysmenorrhoea; and</li> <li>• NOT indicated for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen (Entry 3 of 4)	When the preparation is for oral use and includes indications for use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> </ul>
Ketoprofen (Entry 4 of 4)	In preparations for dermal use	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to ketoprofen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.</li> </ul>
<i>Kunzea ambigua</i> (Entry 1 of 2)	In listed medicines when the preparation is "essential oil"	<ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Keep out of reach of children.</li> <li>• Not to be applied undiluted to the skin except on the advice of a healthcare practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Kunzea ambigua</i> (Entry 2 of 2)	In listed medicines when the preparation is other than “essential oil”	<ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Keep out of reach of children.</li> </ul>
Lactic acid (See <i>Alpha hydroxy acids</i> )	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> <li>• This product may make your skin more sensitive to sunlight and other sources of UV light</li> <li>• Sun exposure should be limited by using a sunscreen and by wearing protective clothing</li> <li>• Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use</li> <li>• If you have sensitive skin, test this product on a small area of skin before applying it to a large area</li> <li>• Not recommended for use on children and infants</li> </ul>
Lactoferrin – bovine	In listed medicines	<ul style="list-style-type: none"> <li>• Derived from cow’s milk.</li> </ul>
Lansoprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
<i>Larrea tridentata</i>	In listed medicines	<ul style="list-style-type: none"> <li>• Warning: Chaparral may harm the liver in some people.</li> <li>• Use only under the supervision of a healthcare professional.</li> </ul>
Lemon oil	For the purpose of exclusion from the schedules of the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
<i>Leptospermum scoparium</i> oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of <i>Leptospermum scoparium</i> oil; and</li> <li>• packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Levocabastine (Entry 1 of 2)	In eye or nasal preparations containing 0.5 milligrams/millilitre or less of levocabastine	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> </ul>
Levocabastine (Entry 2 of 2)	In eye or nasal preparations containing MORE THAN 0.5 milligrams per millilitre of levocabastine.	<ul style="list-style-type: none"> <li>• Do not use if pregnant.</li> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Levocetirizine (Entry 1 of 2)	In preparations for oral use labelled for use in adults	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>– This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> </li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Levocetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> <li>• This medication may cause drowsiness.</li> </ul>
Lignocaine (Entry 1 of 3)	In dermal preparations containing MORE THAN 2 per cent of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• Do not apply to large areas of the body, except on the advice of a healthcare practitioner.</li> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Lignocaine (Entry 2 of 3)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> <li>• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.</li> </ul>
Lignocaine (Entry 3 of 3)	In lozenges	<ul style="list-style-type: none"> <li>• Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth.</li> <li>• Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.</li> </ul>
Lime oil	For the purpose of exclusion from the schedules of the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>
Lindane	In preparations for external use	<ul style="list-style-type: none"> <li>• Do not use on broken skin.</li> <li>• Ask your doctor or pharmacist before use.</li> <li>• This preparation should be used with caution on infants, small children and pregnant or breastfeeding women.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Loperamide hydrochloride	In medicines for oral use	<ul style="list-style-type: none"> <li>• If the condition persists after two days of treatment, seek medical advice as soon as possible.</li> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> <li>• Do not give to children under 12 years of age.</li> <li>• Drink plenty of fluids as fluid and electrolyte depletion may occur with diarrhoea. If dehydration is suspected seek medical attention.</li> <li>• Do not take if you have a medical condition where constipation should be avoided.</li> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing condition affecting the bowel.</li> </ul>
Loratadine	In medicines for oral use	<ul style="list-style-type: none"> <li>• If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.</li> </ul>
Marjoram oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 50 per cent of marjoram oil; and</li> <li>• packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Mefenamic acid	When indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to mefenamic acid or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing mefenamic acid, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Melaleuca oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> <li>• in preparations containing more than 25 per cent of melaleuca oil; and</li> <li>• when packed in containers having: <ul style="list-style-type: none"> <li>– a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or</li> <li>– a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Metoclopramide	In medicines for oral use	<ul style="list-style-type: none"> <li>• Do not use in children and adolescents aged under 18 years.</li> <li>• Tell your doctor or pharmacist before use if you are taking other medicines.</li> <li>• Do not use if you have epilepsy [(seizures)/(fits)].</li> </ul>
Methoxamine	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Miconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if problem returns.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naphazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Naphazoline (Entry 2 of 2)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Naproxen (Entry 1 of 3)	When indicated for oral use exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naproxen (Entry 2 of 3)	<p>In preparations for oral use that are:</p> <ul style="list-style-type: none"> <li>- NOT indicated exclusively for the treatment of dysmenorrhoea; and</li> <li>- NOT indicated for use in children under 12 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naproxen (Entry 3 of 3)	When the preparation includes indications for oral use in children under 12 years of age	<ul style="list-style-type: none"> <li>• Do not use [this product/<i>insert name of product</i>] if you have a stomach ulcer.</li> <li>• Do not use if you have impaired kidney function.</li> <li>• Do not use if you have heart failure.</li> <li>• Do not use [this product/<i>insert name of product</i>] if you are allergic to naproxen or other anti-inflammatory medicines.</li> <li>• If you get an allergic reaction, stop taking and see your doctor immediately.</li> <li>• Unless a doctor has told you to, do not use [this product/<i>insert name of product</i>] if you have asthma.</li> <li>• Unless advised by your doctor or pharmacist, do not use [this product/<i>insert name of product</i>] with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.</li> <li>• Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.</li> <li>• Do not use [this product/<i>insert name of product</i>] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.</li> <li>• Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.</li> </ul>
Nasal decongestant preparations, including: <ul style="list-style-type: none"> <li>• Methoxamine</li> <li>• Naphazoline</li> <li>• Oxymetazoline</li> <li>• Phenylephrine</li> <li>• Tetrahydrozoline</li> <li>• Tramazoline</li> <li>• Tymazoline</li> <li>• Xylometazoline</li> </ul>	When in nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Nizatidine	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks , consult a doctor.</li> </ul>
Nutmeg oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in preparations containing more than 50 per cent of nutmeg oil; and</li> <li>• packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Nystatin	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• See a doctor if you are pregnant or diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• If getting better, keep using for [<i>insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Omega-3 fish oil phytosterol esters	When in listed medicines for oral ingestion	<ul style="list-style-type: none"> <li>• Not suitable for use by pregnant or lactating women.</li> <li>• There is no benefit from taking more than 3 g per day of phytosterols from all sources.</li> </ul>
Omeprazole	In preparations for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Orange oil (bitter)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> <li>• Application to skin may increase sensitivity to sunlight.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Oxymetazoline (Entry 1 of 4)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Oxymetazoline (Entry 2 of 4) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Oxymetazoline (Entry 3 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Oxymetazoline (Entry 4 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pantoprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Paracetamol (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> <li>• Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor.</li> <li>• Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.</li> <li>• If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.</li> <li>• Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.</li> </ul>
Paracetamol (Entry 2 of 2)	In Schedule 2 or 3 to the SUSMP	<ul style="list-style-type: none"> <li>• <ul style="list-style-type: none"> <li>- Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor.</li> </ul> </li> <li><i>and / or</i></li> <li>• <ul style="list-style-type: none"> <li>- Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.</li> </ul> </li> <li>• If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.</li> <li>• Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.</li> </ul>
<i>Paullinia cupana</i>	In listed medicines	<ul style="list-style-type: none"> <li>• The goods contain caffeine.</li> <li>• Each [<i>insert name of dosage unit</i>] contains [<i>insert quantity</i>] of caffeine.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pennyroyal oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in preparations containing more than 4 per cent of d-pulegone; and</li> <li>• when packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> <li>• NOT TO BE TAKEN.</li> </ul>
Pentoxyverine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Pentoxyverine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Permanganates (see also Potassium permanganate)	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li>• <i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Corrosive Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pheniramine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Pheniramine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Pheniramine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Phenol and any other homologue of phenol	When included in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes</li> <li>Avoid contact with skin.</li> </ul> </li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Phenylalanine	In listed medicines for oral or sublingual administration, the MRDD of which contains more than 500 milligrams of phenylalanine	<ul style="list-style-type: none"> <li>• Do not use if pregnant or likely to become pregnant.</li> </ul>
Phenylephrine (Entry 1 of 7)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Phenylephrine (Entry 2 of 7) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Phenylephrine (Entry 3 of 7)	In oral preparations that are NOT indicated for cough, cold or flu	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> </ul>
Phenylephrine (Entry 4 of 7)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> <li>• Do not give to children under 12 years of age.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Phenylephrine (Entry 5 of 7)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• This product may cause sleeplessness.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Phenylephrine Entry 6 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu, which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Phenylephrine (Entry 7 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children under 'x' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pholcodine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu, and the preparation does not include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> <li>• If [coughing/symptoms] persist(s) consult your doctor or pharmacist.</li> </ul>
Pholcodine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s) consult your doctor or pharmacist.</li> </ul>
<i>Piper methysticum</i> (Entry 1 of 2)	In listed medicines for oral use containing more than 25 mg of kavalactones per dose	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or lactating women.</li> <li>• WARNING: Not for prolonged use.</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• May harm the liver.</li> </ul>
<i>Piper methysticum</i> (Entry 2 of 2)	For the purpose of exclusion from the schedules to the SUSMP in medicines for oral use	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or lactating women</li> <li>• WARNING: Not for prolonged use</li> <li>• If symptoms persist, seek advice from a health care practitioner.</li> <li>• May harm the liver.</li> </ul>
Podophyllin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas except on doctor's advice.</li> </ul>
Podophyllin (Entry 1 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Podophyllotoxin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas except on doctor's advice.</li> </ul>
Podophyllotoxin (Entry 2 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> <li>• WARNING - Do not use on face or on anal or genital areas.</li> </ul>
Pollen	When the ingredient is collected by bees and included in listed medicines (including as an excipient).	<ul style="list-style-type: none"> <li>• This product contains pollen which can cause severe allergic reactions.</li> </ul>
Potassium chloride (Entry 1 of 2)	In listed medicines for oral rehydration therapy exclusively for adults	<ul style="list-style-type: none"> <li>• Keep out of reach of children.</li> <li>• Contains [<i>amount of potassium</i>] potassium.</li> <li>• If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> <li>• Use only as directed.</li> <li>• If diarrhoea persists, seek medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)										
Potassium chloride (Entry 2 of 2)	In listed medicines for oral rehydration therapy and indicated for use in children	<ul style="list-style-type: none"> <li>• Keep out of reach of children.</li> <li>• Contains [<i>amount of potassium</i>] potassium.</li> <li>• If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.</li> <li>• Use only as directed.</li> <li>• If diarrhoea persists, seek medical advice.</li> <li>• [<i>include the following additional directions in the 'Directions for Use'</i>]:</li> </ul> <table border="1" data-bbox="820 624 1315 1256"> <thead> <tr> <th data-bbox="820 624 991 689">Age of child</th> <th data-bbox="991 624 1315 689">Additional Directions</th> </tr> </thead> <tbody> <tr> <td data-bbox="820 689 991 831">Under 6 months</td> <td data-bbox="991 689 1315 831">Medical advice should be sought if diarrhoea persists for more than 6 hours</td> </tr> <tr> <td data-bbox="820 831 991 972">Under 3 years</td> <td data-bbox="991 831 1315 972">Medical advice should be sought if diarrhoea persists for more than 12 hours</td> </tr> <tr> <td data-bbox="820 972 991 1113">3 – 6 years</td> <td data-bbox="991 972 1315 1113">Medical advice should be sought if diarrhoea persists for more than 24 hours</td> </tr> <tr> <td data-bbox="820 1113 991 1256">Over 6 years</td> <td data-bbox="991 1113 1315 1256">Medical advice should be sought if diarrhoea persists for more than 48 hours</td> </tr> </tbody> </table>	Age of child	Additional Directions	Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours	Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours	3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours	Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours
Age of child	Additional Directions											
Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours											
Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours											
3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours											
Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours											
Potassium hydroxide (Entry 1 of 3)	When included in a schedule to the SUSMP, in preparations containing 0.5 per cent OR LESS of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>SAFETY DIRECTIONS</b></li> </ul> <p style="margin-left: 20px;">Irritant</p> <p style="margin-left: 20px;">Avoid contact with eyes</p> <p style="margin-left: 20px;">Avoid contact with skin</p> <p style="margin-left: 20px;">Wash hands after use.</p> <ul style="list-style-type: none"> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>										

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Potassium hydroxide (Entry 2 of 3)	When included in a schedule to the SUSMP, in solid preparations containing MORE THAN 0.5 per cent of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using</li> <li>Do not mix with hot water.</li> </ul> </li> </ul>
Potassium hydroxide (Entry 3 of 3)	When included in a schedule to the SUSMP, in liquid preparations containing MORE THAN 0.5 per cent of potassium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using.</li> </ul> </li> </ul>
Potassium permanganate	In Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.</li> </ul> </li> </ul>
Povidone-iodine	In preparations for dermal use	<ul style="list-style-type: none"> <li>• If skin irritation or rash occurs, discontinue use immediately.</li> </ul>
Promethazine (Entry 1 of 4)	When indicated for short term use in insomnia	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or breastfeeding women.</li> <li>• Do not take this medicine for more than a few days.</li> <li>• This product should be taken on medical or pharmacist advice.</li> <li>• This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Promethazine (Entry 2 of 4)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Promethazine (Entry 3 of 4)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> <li><i>or</i></li> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Promethazine (Entry 4 of 4)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li><i>or (if 'x' is 6, 7, 8, 9 or 10)</i></li> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>
Propamidine	In medicines for ophthalmic use	<ul style="list-style-type: none"> <li>• Contact lens wearers should not use this product except on the advice of a doctor or optometrist.</li> <li>• If your eye infection does not improve within 48 hours, seek immediate medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Propolis (Entry 1 of 2)	In listed medicines for internal use	<ul style="list-style-type: none"> <li>• WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use.</li> </ul>
Propolis (Entry 2 of 2)	In listed medicines for external use	<ul style="list-style-type: none"> <li>• WARNING: Propolis may cause skin irritation. Test before use.</li> </ul>
Proton pump inhibitors including: <ul style="list-style-type: none"> <li>• Esomeprazole</li> <li>• Lansoprazole</li> <li>• Omeprazole</li> <li>• Pantoprazole</li> <li>• Rabeprazole</li> </ul>	In medicines for oral use	<ul style="list-style-type: none"> <li>• CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>• If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>• Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Pseudoephedrine (Entry 1 of 3)	When the preparation is NOT indicated for use for cough, cold or flu	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> </ul>
Pseudoephedrine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> <li>• Do not give to children under 12 years of age.</li> </ul>
Pseudoephedrine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication.</li> <li>• [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.</li> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Psyllium	In medicines for oral ingestion which include dosage instructions for children	<ul style="list-style-type: none"> <li>Should only be used for children on medical advice.</li> </ul>
Pyrethrins	When used as an excipient in listed medicines for topical use	<ul style="list-style-type: none"> <li>This product contains pyrethrins [<i>insert quantity</i>]</li> </ul>
Pyridoxal (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</li> </ul>
Pyridoxal (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.</li> </ul>
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</li> </ul>
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> <li>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pyrrithione zinc	In preparations for external use for treatment of the scalp	<i>either</i> <ul style="list-style-type: none"> <li>Keep out of eyes.</li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>If in eyes, rinse well with water.</li> </ul>
Rabeprazole	In medicines for oral use	<ul style="list-style-type: none"> <li>CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>If symptoms persist or recur within two weeks of completing the course, consult a doctor.</li> <li>Ask your doctor or pharmacist before use if you are taking other medicines regularly.</li> </ul>
Ranitidine	Medicines for oral use	<ul style="list-style-type: none"> <li>CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.</li> <li>If symptoms persist or recur within two weeks, consult a doctor.</li> </ul>
Royal jelly	In listed medicines	<ul style="list-style-type: none"> <li>Not suitable for use by children.</li> <li>Not to be taken by asthma and allergy sufferers. <a href="#">[k]</a> <a href="#">[l]</a></li> <li>This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy sufferers.</li> </ul>
Safrole	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS</b> <a href="#">[f]</a></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> <a href="#">[f]</a></li> </ul> </li> <li><b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> </ul>
Sage oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>in preparations containing more than 4 per cent of thujone; and</li> <li>packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure</li> </ul>	<ul style="list-style-type: none"> <li>KEEP OUT OF REACH OF CHILDREN.</li> <li>NOT TO BE TAKEN.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Salbutamol	In metered aerosols or in dry powder formulations	<ul style="list-style-type: none"> <li>This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>
Sassafras oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> <li><i>either</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li><b>SAFETY DIRECTIONS</b> Avoid contact with eyes.</li> </ul>
Selenium yeast – high	In listed medicines	<ul style="list-style-type: none"> <li>This product contains selenium which is toxic in high doses.</li> <li>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Selenocysteine	In listed medicines	<ul style="list-style-type: none"> <li>This product contains selenium which is toxic in high doses.</li> <li>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Selenomethionine	In listed medicines	<ul style="list-style-type: none"> <li>This product contains selenium which is toxic in high doses.</li> <li>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Senega (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>Do not give to children under 12 years of age.</li> <li>If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Senega (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• either (if 'x' is 11)               <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10)               <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>• If [coughing/symptoms] persist(s), consult your doctor or pharmacist.</li> </ul>
Shark cartilage	In listed medicines	<ul style="list-style-type: none"> <li>• Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice.</li> </ul>
Silver (see also Silver salts)	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in chewing gum containing 5 milligrams or less of silver per dosage unit; or</li> <li>• in solutions for oral use containing 0.3 per cent or less of silver</li> </ul>	<ul style="list-style-type: none"> <li>• Overuse may stain skin or mouth.</li> </ul>
Silver salts (see also Silver)	In smoking deterrents.	<ul style="list-style-type: none"> <li>• WARNING - Overuse may stain the skin or mouth.</li> </ul>
Sodium bicarbonate (Entry 1 of 2)	In listed medicines for oral rehydration therapy exclusively for adults	<ul style="list-style-type: none"> <li>• Use only as directed.</li> <li>• If diarrhoea persists, seek medical advice.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)										
Sodium bicarbonate (Entry 2 of 2)	In listed medicines for oral rehydration therapy that are indicated for use in children	<ul style="list-style-type: none"> <li>Use only as directed.</li> <li>If diarrhoea persists, seek medical advice.</li> <li>[include the following additional directions in the 'Directions for Use']:</li> </ul> <table border="1"> <thead> <tr> <th>Age of child</th> <th>Additional Directions</th> </tr> </thead> <tbody> <tr> <td>Under 6 months</td> <td>Medical advice should be sought if diarrhoea persists for more than 6 hours</td> </tr> <tr> <td>Under 3 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 12 hours</td> </tr> <tr> <td>3 – 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 24 hours</td> </tr> <tr> <td>Over 6 years</td> <td>Medical advice should be sought if diarrhoea persists for more than 48 hours</td> </tr> </tbody> </table>	Age of child	Additional Directions	Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours	Under 3 years	Medical advice should be sought if diarrhoea persists for more than 12 hours	3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours	Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours
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Under 6 months	Medical advice should be sought if diarrhoea persists for more than 6 hours											
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3 – 6 years	Medical advice should be sought if diarrhoea persists for more than 24 hours											
Over 6 years	Medical advice should be sought if diarrhoea persists for more than 48 hours											
Sodium fluoride (see also Fluorides)	In preparations for ingestion when in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> <li>Use of this product is not necessary in areas supplied with fluoridated water.</li> </ul>										
Sodium hydroxide (Entry 1 of 3)	When included in a schedule to the SUSMP, in preparations containing 0.5 per cent or less of sodium hydroxide	<ul style="list-style-type: none"> <li>either <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS [f]</b></li> </ul> </li> <li>or <ul style="list-style-type: none"> <li><b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li><b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Irritant</li> <li>Avoid contact with eyes</li> <li>Avoid contact with skin</li> <li>Wash hands after use.</li> </ul> </li> <li><b>DO NOT SWALLOW. [g]</b></li> </ul>										

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Sodium hydroxide (Entry 2 of 3)	When included in a schedule to the SUSMP, in solid preparations containing more than 0.5 per cent of sodium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using</li> <li>Do not mix with hot water.</li> </ul> </li> </ul>
Sodium hydroxide (Entry 3 of 3)	When included in a schedule to the SUSMP, in liquid preparations containing more than 0.5 per cent of sodium hydroxide	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> <ul style="list-style-type: none"> <li>Corrosive</li> <li>May produce severe burns</li> <li>Attacks skin and eyes</li> <li>Wear eye protection when mixing or using</li> <li>Wear protective gloves when mixing or using.</li> </ul> </li> </ul>
Sodium selenate	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Sodium selenite	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Sodium sulfate	In listed medicines	<ul style="list-style-type: none"> <li>• This preparation may have a laxative effect.</li> </ul>
Squid oil	In listed medicines	<ul style="list-style-type: none"> <li>• <b>DERIVED FROM SEAFOOD</b></li> </ul>
(S)-S-Adenosylmethionine	In listed medicines, in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	<ul style="list-style-type: none"> <li>• Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Star anise oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in preparations containing more than 50 per cent of star anise oil; and</li> <li>• packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Sugar cane wax alcohols	In listed medicines	<ul style="list-style-type: none"> <li>• Not recommended for use by pregnant or lactating women.</li> </ul>
Sulfacetamide	In medicines for ophthalmic use	<ul style="list-style-type: none"> <li>• Contact lens wearers should not use this product except on the advice of a doctor or optometrist.</li> <li>• If your eye infection does not improve within 48 hours, seek immediate medical advice.</li> </ul>
<i>Symphytum</i> spp	In Schedule 5 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS [f]</b></li> <li><i>or</i></li> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f]</b></li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Do not use on broken skin Do not use under occlusive dressing.</li> <li>• <b>DO NOT SWALLOW. [g]</b></li> </ul>
Terbutaline	In metered aerosols	<ul style="list-style-type: none"> <li>• This preparation should be part of an overall treatment plan regularly assessed with your doctor.</li> </ul>
Tetrahydrozoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Tetrahydrozoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Thyme oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> <li>• in preparations containing more than 50 per cent of thyme oil; and</li> <li>• packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert</li> </ul>	<ul style="list-style-type: none"> <li>• KEEP OUT OF REACH OF CHILDREN.</li> </ul>
Tioconazole	In preparations for vaginal use	<ul style="list-style-type: none"> <li>• Do not use if you are pregnant.</li> <li>• See a doctor before use if you are diabetic.</li> <li>• Seek medical advice before first course of treatment.</li> <li>• See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> <li>• See a doctor if problem returns.</li> </ul>
Tramazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>• If congestion persists, consult your doctor or pharmacist.</li> <li>• Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>• Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Tramazoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>• Prolonged use may be harmful.</li> <li>• Consult a doctor or pharmacist if using other eye products.</li> <li>• Do not use if you have glaucoma or other serious eye conditions.</li> <li>• If symptoms persist, consult a doctor or pharmacist.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Triamcinolone	In topical preparations for the treatment of mouth ulcers	<i>either</i> <ul style="list-style-type: none"> <li>• See a [doctor / doctor or dentist] if no better after [<i>Insert number of days as per approved Product Information</i>] days.</li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>• If symptoms persist beyond 5 days consult a [doctor / doctor or dentist].</li> </ul>
Triprolidine (Entry 1 of 3)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 12 years of age.</li> </ul>
Triprolidine (Entry 2 of 3)	In oral preparations indicated for cough, cold or flu which include dosage instructions for adults and children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.</li> </ul> </li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.</li> </ul> <ul style="list-style-type: none"> <li>• Do not give to children under 'x' years of age.</li> <li>• <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul> <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> <li>- Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul>



Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Triprolidine (Entry 3 of 3)	In oral preparations indicated for cough, cold or flu which only include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>
Tymazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Tymazoline (Entry 2 of 2) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Ubidecarenone	In listed medicines	<ul style="list-style-type: none"> <li>Not to be taken, if on warfarin therapy, without medical advice.</li> </ul>
Ubiquinol-10	In listed medicines	<ul style="list-style-type: none"> <li>Not to be taken, if on warfarin therapy, without medical advice.</li> </ul>
Vasoconstrictor eye drops including: <ul style="list-style-type: none"> <li>Naphazoline</li> <li>Oxymetazoline</li> <li>Phenylephrine</li> <li>Tetrahydrozoline</li> <li>Tramazoline</li> <li>Tymazoline</li> <li>Xylometazoline</li> </ul>	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Vegetable oil phytosterol esters	In preparations for oral ingestion	<ul style="list-style-type: none"> <li>Not suitable for use by pregnant or lactating women.</li> <li>There is no benefit from taking more than 3 g/day of phytosterols from all sources.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Vitamin A <i>(See also Vitamins)</i>	In medicines for oral use that are labelled to be used by females of childbearing age containing MORE THAN: <ul style="list-style-type: none"> <li>• 33 micrograms retinol equivalents of vitamin A per dosage unit of a divided preparation; or</li> <li>• 33 micrograms retinol equivalents of vitamin A per gram of an undivided preparation</li> </ul>	<ul style="list-style-type: none"> <li>• <b>The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.</b></li> <li>• <b>WARNING – When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.</b> <a href="#">[c]</a></li> <li>• <b>If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.</b> <a href="#">[c]</a></li> </ul>
Vitamin B6 <ul style="list-style-type: none"> <li>• pyridoxal</li> <li>• pyridoxine</li> </ul> <i>(Entry 1 of 2)</i> <i>(See also Vitamins)</i>	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> <li>• <b>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.</b></li> </ul>
Vitamin B6 <ul style="list-style-type: none"> <li>• pyridoxal</li> <li>• pyridoxine</li> </ul> <i>(Entry 2 of 2)</i> <i>(See also Vitamins)</i>	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> <li>• <b>WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.</b></li> </ul>
Vitamins <i>(see also: Pyridoxal, Pyridoxine, Vitamin A, Vitamin B6)</i>	In listed medicines	<i>either</i> <ul style="list-style-type: none"> <li>• Vitamins can only be of assistance if the dietary vitamin intake is inadequate.</li> </ul> <i>or</i> <ul style="list-style-type: none"> <li>• Vitamin supplements should not replace a balanced diet.</li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Wheat dextrin	When used as an excipient in listed medicines for oral use	<ul style="list-style-type: none"> <li>Contains gluten.</li> </ul>
Xylometazoline (Entry 1 of 4)	When in nasal decongestant preparations for topical use	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> </ul>
Xylometazoline (Entry 2 of 4) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> <li>Prolonged use may be harmful.</li> <li>Consult a doctor or pharmacist if using other eye products.</li> <li>Do not use if you have glaucoma or other serious eye conditions.</li> <li>If symptoms persist, consult a doctor or pharmacist.</li> </ul>
Xylometazoline (Entry 3 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>Do not give to children under 12 years of age.</li> </ul>
Xylometazoline (Entry 4 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> <li>If congestion persists, consult your doctor or pharmacist.</li> <li>Do not use for more than three days at a time unless advised by a doctor or pharmacist.</li> <li>Frequent or prolonged use may cause nasal congestion to recur or worsen.</li> <li>Do not give to children under 'x' years of age.</li> <li>either (if 'x' is 11) <ul style="list-style-type: none"> <li>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> <li>or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> <li>Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.</li> </ul> </li> </ul>

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Yeast – high selenium	In listed medicines	<ul style="list-style-type: none"> <li>• This product contains selenium which is toxic in high doses.</li> <li>• A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.</li> </ul>
Zinc chloride	In a schedule to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes Avoid contact with skin.</li> </ul>
Zinc compounds	In preparations for internal use with a recommended daily dose of more than 25 milligrams of zinc	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>• WARNING - This medication may be dangerous when used in large amounts or for a long period.</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>• WARNING – Contains zinc, which may be dangerous when used in large amounts or for a long period.</li> </ul> </li> </ul>
Zinc sulfate	In Schedule 6 to the SUSMP	<ul style="list-style-type: none"> <li>• <i>either</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS</b> [f]</li> </ul> </li> <li><i>or</i> <ul style="list-style-type: none"> <li>- <b>READ SAFETY DIRECTIONS BEFORE OPENING AND USING.</b> [f]</li> </ul> </li> <li>• <b>SAFETY DIRECTIONS</b> Avoid contact with eyes Avoid contact with skin.</li> </ul>
<i>Zingiber officinale</i>	In listed medicines: <ul style="list-style-type: none"> <li>• when the extraction ratio is 25:1 or higher; and</li> <li>• when the equivalent dry weight per dosage unit is 2 grams or higher</li> </ul>	<ul style="list-style-type: none"> <li>• Individuals taking anticoagulants should seek medical advice before taking this product.</li> <li>• Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product.</li> </ul>