

**PB 1 of 2024**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2024
(No. 1)**

*National Health Act 1953*

I, NIKOLAI TSYGANOV, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 31 January 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

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Schedule 1—Amendments 2

National Health (Listing of Pharmaceutical Benefits) Instrument 2012
(PB 71 of 2012). 2

1 Name

1. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2024 (No. 1)*.
2. This instrument may also be cited as PB 1 of 2024.

2 Commencement

1. Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information |
| --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. *The whole of this instrument* | *1 February 2024* | *1 February 2024* |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

1. Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

*National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)*

1. **Schedule 1, Part 1, entry for Acarbose in the form Tablet 100 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Acarbose Mylan | AF | MP NP |  |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, Part 1, entry for Amantadine**
2. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | AMANTAMED | DZ | MP NP | C5132 |  | 100 | 5 | 100 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Symmetrel 100”:* **a**
2. **Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 10 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ambrisentan Mylan | AF | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without methionine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachets containing oral powder 24 g, 30 (HCU gel) | Oral |  | HCU gel | VF | MP NP | C5534 |  | 4 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without phenylalanine and tyrosine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachets containing oral powder 24 g, 30 (TYR gel) | Oral |  | TYR gel | VF | MP NP | C5533 |  | 4 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachets containing oral powder 24 g, 30 (MSUD gel) | Oral |  | MSUD gel | VF | MP NP | C5571 |  | 4 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Amisulpride in the form Tablet 100 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amisulpride 100 Winthrop | WA | MP NP | C4246 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besilate); and Tablet 10 mg (as besilate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amlodipine Amneal | EF | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amlodipine Amneal | EF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | a | AlphaClav Duo | AF | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO 500/125 | RW | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Amoxycillin/Clavulanic Acid 500/125 APOTEX | TY | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APO-AMOXY/CLAV 500/125 | TW | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | APX-Amoxicillin/Clavulanic Acid | XT | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo | AS | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo 500/125 | SZ | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MW | C5832 C5893 |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |
|  |  |  | a | AlphaClav Duo | AF | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | AMCLAVOX DUO 500/125 | RW | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Amoxycillin/Clavulanic Acid 500/125 APOTEX | TY | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | APO-AMOXY/CLAV 500/125 | TW | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | APX-Amoxicillin/Clavulanic Acid | XT | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Augmentin Duo | AS | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |
|  |  |  | a | Curam Duo 500/125 | SZ | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Amoxyclav AN 875/125 | EA | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | PDP | C5833 C5894 |  | 10 | 0 | 10 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Amoxyclav AN 875/125 | EA | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Aripiprazole in each of the forms: Tablet 10 mg; Tablet 15 mg; and Tablet 20 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | ARIZOLE | RW | MP NP | C4246 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Aripiprazole in the form Tablet 30 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Aripiprazole generichealth | HQ | MP NP | C4246 |  | 30 | 5 | 30 |  |  |

1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | ARIZOLE | RW | MP NP | C4246 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Atenolol in the form Tablet 50 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Atenolol Amneal | EF | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Atenolol Amneal | EF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Azathioprine in the form Tablet 50 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Azathioprine GH  | GQ  | MP NP  |  |  | 100  | 5  | 100  |  |  |

1. **Schedule 1, Part 1, entry for Bleomycin**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | CIPLA BLEOMYCIN | LR | MP | C6224 C6275 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Bosentan Cipla  | LR  | MP  | See Note 3  | See Note 3  | See Note 3  | See Note 3  | 60  |  | D(100)  |

1. **Schedule 1, Part 1, entry for Calcitriol**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Calcitriol AN | EA | MP NP | C5089 C5114 C5255 C5401 C5402 C14231 C14259 C14287 C14296 C14322 | P5089 P5114 P5255 P5401 P5402 | 100 | 3 | 100 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Calcitriol AN | EA | MP NP | C5089 C5114 C5255 C5401 C5402 C14231 C14259 C14287 C14296 C14322 | P14231 P14259 P14287 P14296 P14322 | 200 | 3 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Cefepime in each of the forms: Powder for injection 1 g (as hydrochloride); and Powder for injection 2 g (as hydrochloride)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cefepime Alphapharm | AF | MP NP | C5842 |  | 10 | 0 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Cinacalcet in the form Tablet 60 mg (as hydrochloride)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cinacalcet Mylan | AF | MP NP | C10068 |  | 28 | 5 | 28 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cinacalcet Mylan | AF | MP | C10063 C10067 C10073 |  | 56 | 5 | 28 |  | C(100) |

1. **Schedule 1, Part 1, entry for Citalopram in the form Tablet 10 mg (as hydrobromide)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Citalopram AN | EF | MP NP | C4755 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Citalopram in each of the forms: Tablet 20 mg (as hydrobromide); and Tablet 40 mg (as hydrobromide)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Citalopram AN | EA | MP NP | C4755 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Clarithromycin in the form Tablet 250 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Clarithromycin AN  | EA  | MP NP  |  |  | 14  | 1  | 14  |  |  |

1. **Schedule 1, Part 1, entry for Colestyramine**

*insert as first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sachet containing 4 g oral powder (s19A) | Oral |  | Cholestyramine-Odan | DZ | MP NP |  |  | 100 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P6429 | 100 | 11 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cyprone 50 | AL | MP |  | P5532 | 20CN5532 | 5CN5532 | 20 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cyprone 50 | AL | MP |  |  | 100 | 5 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cyprone 100 | AF | MP |  |  | 50 | 5 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Deferasirox in the form Tablet 90 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7385 P8326 P8328 P8329 P9222 P9258 P9302 | 180 | 2 | 30 |  | D(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7374 P7375 | 180 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Deferasirox in the form Tablet 180 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7385 P8326 P8328 P8329 P9222 P9258 P9302 | 180 | 2 | 30 |  | D(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7374 P7375 | 180 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Deferasirox in the form Tablet 360 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7385 P8326 P8328 P8329 P9222 P9258 P9302 | 180 | 2 | 30 |  | D(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | CIPLA DEFERASIROX | LR | MP | C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302 | P7374 P7375 | 180 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Desvenlafaxine in the form Tablet (modified release) 50 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Desvenlafaxine Actavis | EA | MP NP | C5650 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Desvenlafaxine in the form Tablet (modified release) 100 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Desvenlafaxine Actavis | EA | MP NP | C5650 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 25 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Diclofenac AN | EA | PDP |  |  | 100 | 0 | 50 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Diclofenac AN | EA | MP NP |  |  | 100 | 3 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 50 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Diclofenac AN | EA | PDP |  |  | 50 | 0 | 50 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Diclofenac AN | EA | MP NP |  |  | 50 | 3 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Diltiazem in the form Tablet containing diltiazem hydrochloride 60 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Diltiazem AN  | EA  | MP NP  |  |  | 90  | 5  | 90  |  |  |

1. **Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/10 | LR | MP NP | C7958 C14269 | P7958 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/10 | LR | MP NP | C7958 C14269 | P14269 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/20 | LR | MP NP | C7958 C14269 | P7958 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/20 | LR | MP NP | C7958 C14269 | P14269 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/40 | LR | MP NP | C7957 C14284 | P7957 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/40 | LR | MP NP | C7957 C14284 | P14284 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/80 | LR | MP NP | C7957 C14284 | P7957 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZEVYT 10/80 | LR | MP NP | C7957 C14284 | P14284 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Famciclovir in the form Tablet 125 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Famciclovir-GA | ED | MP NP | C5937 |  | 40 | 1 | 40 |  |  |

1. **Schedule 1, Part 1, entry for Famciclovir in the form Tablet 250 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Famciclovir-GA | ED | MP NP | C5937 C5951 | P5937 | 20 | 1 | 20 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Famciclovir-GA | ED | MP NP | C5937 C5951 | P5951 | 21 | 0 | 21 |  |  |

1. **Schedule 1, Part 1, entry for Famciclovir in the form Tablet 500 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Famciclovir-GA | ED | MP NP | C5947 C5948 C5949 C5954 |  | 56 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Fluoxetine**

*insert as first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 10 mg (Medreich) (S19A) | Oral |  | Fluoxetine Capsules 10 mg (Medreich, UK) | LM | MP NP | C14828 C14832 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Seroflo 125/25  | YC  | MP NP  | C4930  |  | 1  | 5  | 1  |  |  |

1. **Schedule 1, Part 1, entry for Fluticasone propionate with salmeterol in the form Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Seroflo 250/25  | YC  | MP NP  | C4930 C10121  |  | 1  | 5  | 1  |  |  |

1. **Schedule 1, Part 1, entry for Furosemide in each of the forms: Tablet 20 mg; and Tablet 40 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | FUROSEMIDE AN | EA | MP NP |  |  | 100 | 1 | 100 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | FUROSEMIDE AN | EA | MP NP |  | P14238 | 200 | 1 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Gabapentin in the form Tablet 600 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Gabapentin AN | EA | MP NP | C4928 |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Gliclazide in the form Tablet 30 mg (modified release)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Gliclazide MR Viatris  | AL  | MP NP  |  |  | 100  | 5  | 100  |  |  |

1. **Schedule 1, Part 1, entry for Glimepiride in the form Tablet 2 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Amaryl | SW | MP NP |  |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Ipilimumab in each of the forms: Injection concentrate for I.V. infusion 50 mg in 10 mL; and Injection concentrate for I.V. infusion 200 mg in 40 mL**
2. *omit from the column headed “Circumstances”:* **C13841**
3. *insert in numerical order in the column headed “Circumstances”:* **C14808**
4. **Schedule 1, Part 1, entry for Irbesartan in the form Tablet 75 mg**
5. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Irbesartan AMNEAL | EF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Irbesartan AN | EA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Irbesartan AMNEAL | EF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Irbesartan AN | EA | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Irbesartan in the form Tablet 300 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Irbesartan AN | EA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Irbesartan AN | EA | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Irinotecan in each of the forms: I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL; and I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | MEDITAB IRINOTECAN | LR | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Isosorbide mononitrate in the form Tablet 60 mg (sustained release)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Isosorbide AN | EA | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Monodur 60 mg | IY | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Isosorbide AN | EA | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Monodur 60 mg | IY | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Rocta 10  | RW  | MP  | C5224  |  | 60  | 3  | 60  |  |  |

1. **Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Rocta 20  | RW  | MP  | C5224  |  | 60  | 3  | 60  |  |  |

1. **Schedule 1, Part 1, entry for Meloxicam in each of the forms: Capsule 7.5 mg; and Capsule 15 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Chem mart Meloxicam | CH | MP NP | C4907 C4962 |  | 30 | 3 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Terry White Chemists Meloxicam | TW | MP NP | C4907 C4962 |  | 30 | 3 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Metformin AN | EA | MP NP |  |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 850 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Chem mart Metformin | CH | MP NP |  |  | 60 | 5 | 60 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Metformin AN | EA | MP NP |  |  | 60 | 5 | 60 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Terry White Chemists Metformin | TW | MP NP |  |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Metformin AN | EA | MP NP |  |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, Part 1, entry for Methotrexate in the form Solution concentrate for I.V. infusion 1000 mg in 10 mL vial**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Pfizer Australia Pty Ltd | PF | MP |  |  | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  |  |  | MP |  | P6276 | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. **Schedule 1, Part 1, entry for Methylprednisolone in the form Cream containing methylprednisolone aceponate 1 mg per g, 15 g**

*omit from the column headed “Responsible Person” for the brand “Supriad Cream” (all instances):* **LG** *substitute (all instances):* **XT**

1. **Schedule 1, Part 1, entry for Methylprednisolone in the form Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g**

*omit from the column headed “Responsible Person” for the brand “Supriad Fatty Ointment” (all instances):* **LG** *substitute (all instances):* **XT**

1. **Schedule 1, Part 1, entry for Methylprednisolone in the form Ointment containing methylprednisolone aceponate 1 mg per g, 15 g**

*omit from the column headed “Responsible Person” for the brand “Supriad Ointment” (all instances):* **LG** *substitute (all instances):* **XT**

1. **Schedule 1, Part 1, entry for Metoclopramide in the form Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metoclopramide | Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL | Injection |  | METOCLOPRAMIDE INJECTION BP | WZ | MP NP MW PDP |  |  | 10 | 0 | 10 |  |  |
|  |  |  |  |  |  | MP NP |  | P6084 | 40CN6084 | 2CN6084 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 15 mg (orally disintegrating)**
2. *omit from the column headed “Schedule Equivalent” for the brand “MIRTANZA ODT”:* **a**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazapine AN ODT | EA | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 30 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazon | RW | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 30 mg (orally disintegrating)**
2. *omit from the column headed “Schedule Equivalent” for the brand “MIRTANZA ODT”:* **a**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazapine AN ODT | EA | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 45 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazon | RW | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Mirtazapine in the form Tablet 45 mg (orally disintegrating)**
2. *omit from the column headed “Schedule Equivalent” for the brand “MIRTANZA ODT”:* **a**
3. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Mirtazapine AN ODT | EA | MP NP | C5650 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Moclobemide in each of the forms: Tablet 150 mg; and Tablet 300 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Moclobemide AN | EA | MP NP | C5650 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid | Oral | a | Mycophenolic Acid ARX | XT | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Myfortic | NV | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Mycophenolic Acid ARX | XT | MP |  | P4084 P4095 P9692 P9809 | 240CN4084 CN4095 CN9692 CN9809 | 5CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | Myfortic | NV | MP |  | P4084 P4095 P9692 P9809 | 240CN4084 CN4095 CN9692 CN9809 | 5CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |

1. **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid | Oral | a | Mycophenolic Acid ARX | XT | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | MYCOTEX | CR | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Myfortic | NV | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Mycophenolic Acid ARX | XT | MP |  | P4084 P4095 P9692 P9809 | 240CN4084 CN4095 CN9692 CN9809 | 5CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | MYCOTEX | CR | MP |  | P4084 P4095 P9692 P9809 | 240CN4084 CN4095 CN9692 CN9809 | 5CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | Myfortic | NV | MP |  | P4084 P4095 P9692 P9809 | 240CN4084 CN4095 CN9692 CN9809 | 5CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |

1. **Schedule 1, Part 1, entry for Natalizumab**

*insert as the first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 150 mg in 1 mL single dose pre-filled syringe | Injection |  | Tysabri | BD | MP | C13625 C13718 |  | 2 | 5 | 2 |  | D(100) |

1. **Schedule 1, Part 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride) *[Maximum Quantity: 56; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nebivolol Viatris | AL | MP NP | C5324 C14251 | P5324 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride) *[Maximum Quantity: 112; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nebivolol Viatris | AL | MP NP | C5324 C14251 | P14251 | 112 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Nebivolol in the form Tablet 10 mg (as hydrochloride) *[Maximum Quantity: 28; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nebivolol Viatris | AL | MP NP | C5324 C14251 | P5324 | 28 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Nebivolol in the form Tablet 10 mg (as hydrochloride) *[Maximum Quantity: 56; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Nebivolol Viatris | AL | MP NP | C5324 C14251 | P14251 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Nitrofurantoin in each of the forms: Capsule 50 mg; and Capsule 100 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | APO-Nitrofurantoin | TX | MP NP MW |  |  | 30 | 1 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Nivolumab in each of the forms: Injection concentrate for I.V. infusion 40 mg in 4 mL; and Injection concentrate for I.V. infusion 100 mg in 10 mL**
2. *omit from the column headed “Circumstances”:* **C10155**
3. *omit from the column headed “Circumstances”:* **C13853**
4. *insert in numerical order in the column headed “Circumstances”:* **C14816 C14830**
5. **Schedule 1, Part 1, after entry for Nivolumab in the form Injection concentrate for I.V. infusion 100 mg in 10 mL**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nivolumab with relatlimab | Solution concentrate for I.V. infusion containing 240 mg nivolumab and 80 mg relatlimab in 20 mL | Injection |  | Opdualag | BQ | MP | C14812 C14815 C14819 C14829 | P14812 P14819 | 2 | 8 | 1 |  | D(100) |
|  |  |  |  |  |  | MP | C14812 C14815 C14819 C14829 | P14815 P14829 | 2 | 11 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Octreotide in the form Injection 100 micrograms (as acetate) in 1 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 100 micrograms (as acetate) in 1 mL | Injection | a | Octreotide (SUN) | RA | MP | C6369 C6390 C8165 C9232 C9233 C9289 |  | 90 | 11 | 5 |  | D(100) |
|  |  |  | a | Octreotide GH | HQ | MP | C6369 C6390 C8165 C9232 C9233 C9289 |  | 90 | 11 | 5 |  | D(100) |
|  |  |  | a | Sandostatin 0.1 | NV | MP | C6369 C6390 C8165 C9232 C9233 C9289 |  | 90 | 11 | 5 |  | D(100) |

1. **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5743 |  | 4 | 0 | 4 |  | C(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Ondansetron AN ODT | EA | MP NP | C5618 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P4118 | 4 | 0 | 4 |  |  |
|  |  |  |  |  |  | MP | C5778 |  | 4 | 0 | 4 |  | C(100) |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ondansetron AN | EA | MP NP | C4118 C10498 | P10498 | 10 | 1 | 10 |  |  |

1. **Schedule 1, Part 1, entry for Palonosetron**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | PALONOSETRON Medsurge | DZ | MP NP | C5686 |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP | C5805 |  | 1 | 0 | 1 |  | C(100) |

1. **Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pantoprazole AN | EA | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P8774 P8775 | 30 | 1 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8866 | P8774 P8775 | 30 | 1 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pantoprazole AN | EA | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P8776 P8780 P8866 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C8774 C8775 C8776 C8780 C8866 | P8776 P8780 P8866 | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Pantoprazole AN | EA | MP | C8774 C8775 C8776 C8780 C8866 C11310 | P11310 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Paroxetine**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Paroxetine AN | EA | MP NP | C4755 C6277 C6636 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Pegfilgrastim**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Ristempa | JO | MP | C7822 C7843 C9235 C9303 |  | 1 | 11 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Pembrolizumab**
2. *omit from the column headed “Circumstances”:* **C10689 C10696**
3. *insert in numerical order in the column headed “Circumstances”:* **C14817 C14818**
4. **Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg**
5. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Perindopril generichealth | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Perindopril generichealth | GQ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Perindopril generichealth | GQ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Perindopril generichealth | GQ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Quetiapine AN  | EA  | MP NP  | C4246 C5611 C5639  |  | 90  | 5  | 90  |  |  |

1. **Schedule 1, Part 1, entry for Quetiapine in the form Tablet 300 mg (as fumarate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | Quetiapine AN  | EA  | MP NP  | C4246 C5611 C5639  |  | 60  | 5  | 60  |  |  |

1. **Schedule 1, Part 1, entry for Ramipril in the form Capsule 1.25 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ramipril | Capsule 1.25 mg | Oral |  | Tryzan Caps 1.25 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Rizatriptan AN ODT  | EA  | MP NP  | C5708  |  | 4  | 5  | 2  |  |  |

1. **Schedule 1, Part 1, after entry for Salbutamol in the form Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A) | Inhalation |  | pms-SALBUTAMOL | DZ | MP NP | C6815 C6825 |  | 3 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Salbutamol in the form Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Salbutamol AN | ED | MP NP | C6815 C6825 |  | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Sertraline in each of the forms: Tablet 50 mg (as hydrochloride); and Tablet 100 mg (as hydrochloride)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Sertraline AN | EA | MP NP | C4755 C6277 C6289 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Sildenafil**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Sildenafil AN PHT 20 | EA | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 90 |  | D(100) |

1. **Schedule 1, Part 1, after entry for Tapentadol in the form Tablet (modified release) 250 mg (as hydrochloride)**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tebentafusp | Solution concentrate for I.V. infusion 100 micrograms in 0.5 mL | Injection |  | Kimmtrak | WM | MP | C14813 C14821 C14822 C14825 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, Part 1, entry for Tenofovir in the form Tablet containing tenofovir disoproxil maleate 300 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing tenofovir disoproxil maleate 300 mg | Oral |  | Tenofovir Disoproxil Mylan | AF | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P10362 | 60 | 2 | 30 |  | D(100) |
|  |  |  |  | Tenofovir Disoproxil Viatris | AL | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P10362 | 60 | 2 | 30 |  | D(100) |
|  |  |  |  | Tenofovir Disoproxil Mylan | AF | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 | 30 |  | D(100) |
|  |  |  |  | Tenofovir Disoproxil Viatris | AL | MP NP | C6980 C6982 C6983 C6984 C6992 C6998 C10362 | P6980 P6982 P6983 P6984 P6992 P6998 | 60 | 5 | 30 |  | D(100) |

1. **Schedule 1, Part 1, entry for Tenofovir with emtricitabine and efavirenz**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600 | AF | MP NP | C4470 C4522 |  | 60 | 5 | 30 |  | D(100) |

1. *omit from the column headed “Schedule Equivalent” for the brand “Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600”:* **a**
2. **Schedule 1, Part 1, entry for Terbinafine in the form Cream containing terbinafine hydrochloride 10 mg per g, 15 g**

*omit from the column headed “Responsible Person”:* **GJ** *substitute:* **NP**

1. **Schedule 1, Part 1, entry for Tobramycin in the form Injection 80 mg in 2 mL**
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Tobramycin Mylan | AF | MP NP | C5446 C5490 C5519 |  | 10 | 1 | 5 |  |  |

1. *omit from the column headed “Schedule Equivalent” for the brand “Tobramycin Viatris”:* **a**
2. **Schedule 1, Part 1, entry for Trientine**
3. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Trientine Dr. Reddy's | RZ | MP NP | C13321 |  | 200 | 5 | 100 |  |  |

1. *insert in the column headed “Schedule Equivalent” for the brand “Trientine Waymade”:* **a**
2. **Schedule 1, Part 1, entry for Varenicline in the form Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a  | VARENAPIX  | TX  | MP NP  | C6871  |  | 1  | 0  | 1  |  |  |

1. **Schedule 1, Part 2, omit entry for Amino acid formula with vitamins and minerals without phenylalanine**
2. **Schedule 1, Part 2, omit entry for Efavirenz**
3. **Schedule 1, Part 2, omit entry for Eprosartan**
4. **Schedule 1, Part 2, omit entry for Ertugliflozin**
5. **Schedule 1, Part 2, omit entry for Ertugliflozin with sitagliptin**
6. Schedule 3

*omit:*

|  |  |  |
| --- | --- | --- |
| CH | Apotex Pty Ltd |  52 096 916 148 |

1. Schedule 3
	1. *omit:*

|  |  |  |
| --- | --- | --- |
| EF | Amneal Pharmaceuticals Pty Ltd |  11 163 167 851 |

1. Schedule 3
	1. *omit:*

|  |  |  |
| --- | --- | --- |
| LG | Leo Pharma Pty Ltd | 72 147 880 617 |

1. Schedule 3, after details relevant to Responsible Person code NO
	1. *insert:*

|  |  |  |
| --- | --- | --- |
| NP | Nice-Pak Products Pty. Ltd | 71 051 956 346 |

1. Schedule 3, after details relevant to Responsible Person code WA
	1. *insert:*

|  |  |  |
| --- | --- | --- |
| WM | MEDISON PHARMA AUSTRALIA PTY LIMITED | 19 659 723 403 |

1. **Schedule 4, Part 1, omit entry for Efavirenz**
2. **Schedule 4, Part 1, omit entry for Ertugliflozin**
3. **Schedule 4, Part 1, omit entry for Ertugliflozin with sitagliptin**
4. **Schedule 4, Part 1, entry for Fluoxetine**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14828 |  |  | Obsessive-compulsive disorderPatient must be receiving this drug under this restriction at a dose of 10 mg; ORPatient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose. |  |
|  | C14832 |  |  | Major depressive disordersPatient must be receiving this drug under this restriction at a dose of 10 mg; ORPatient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose. |  |

1. **Schedule 4, Part 1, entry for Ipilimumab**
2. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C13841 |  |  | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 13841 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14808 |  |  | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14808 |

1. **Schedule 4, Part 1, entry for Nivolumab**
2. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10155 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 10155 |

1. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C13853 |  |  | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 13853 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14816 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 14816 |
|  | C14830 |  |  | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 14830 |

1. **Schedule 4, Part 1, after entry for Nivolumab**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Nivolumab with relatlimab | C14812 | P14812 |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be uveal melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.Patient must weigh 40 kg or more; ANDPatient must be at least 12 years of age.Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 14812 |
|  | C14815 | P14815 |  | Unresectable Stage III or Stage IV malignant melanomaContinuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 14815 |
|  | C14819 | P14819 |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be uveal melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.Patient must weigh 40 kg or more; ANDPatient must be at least 12 years of age.Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 14819 |
|  | C14829 | P14829 |  | Unresectable Stage III or Stage IV malignant melanomaContinuing treatmentPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 14829 |

1. **Schedule 4, Part 1, entry for Pembrolizumab**
2. *omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10689 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 6 weekly treatment regimenPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10689 |
|  | C10696 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 3 weekly treatment regimenPatient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10696 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14817 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 6 weekly treatment regimenPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14817 |
|  | C14818 |  |  | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 3 weekly treatment regimenPatient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; ANDPatient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14818 |

1. **Schedule 4, Part 1, after entry for Tapentadol**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tebentafusp | C14813 |  |  | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 1Patient must have HLA-A\*02:01-positive disease; ANDPatient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must not have received prior systemic therapy for metastatic disease.Patient must be at least 18 years of age.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures |
|  | C14821 |  |  | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 8Patient must have HLA-A\*02:01-positive disease; ANDPatient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14821 |
|  | C14822 |  |  | Advanced (unresectable or metastatic) uveal melanomaContinuing treatmentThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. | Compliance with Authority Required procedures - Streamlined Authority Code 14822 |
|  | C14825 |  |  | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 15Patient must have HLA-A\*02:01-positive disease; ANDPatient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14825 |

1. **Schedule 5, entry for Amoxicillin with clavulanic acid**

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Amoxicillin with clavulanic acid | GRP-26768 | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) | Oral | AMCLAVOX DUO FORTE 875/125APO-AMOXY/CLAV 875/125APO-Amoxycillin and Clavulanic AcidAPX-Amoxicillin/Clavulanic AcidAlphaClav Duo ForteAlphaclav Duo Forte ViatrisAmoxyClav generichealth 875/125Augmentin Duo forteBlooms The Chemist Amoxicillin/Clavulanic Acid 875/125Curam Duo Forte 875/125 |
|  |  | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A) | Oral | Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge)Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals)Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs) |

1. **Schedule 5, entry for Desvenlafaxine in the form Tablet (modified release) 100 mg *[GRP-16219]***

*omit from the column headed “Brand”:* **Desvenlafaxine Actavis**

1. **Schedule 5, entry for Desvenlafaxine in the form Tablet (modified release) 50 mg *[GRP-16220]***

*omit from the column headed “Brand”:* **Desvenlafaxine Actavis**

1. **Schedule 5, entry for Meloxicam in the form Capsule 15 mg *[GRP-15468]***
2. *omit from the column headed “Brand”:* **Chem mart Meloxicam**
3. *omit from the column headed “Brand”:* **Terry White Chemists Meloxicam**
4. **Schedule 5, entry for Meloxicam in the form Capsule 7.5 mg *[GRP-15658]***
5. *omit from the column headed “Brand”:* **Chem mart Meloxicam**
6. *omit from the column headed “Brand”:* **Terry White Chemists Meloxicam**
7. **Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-15402]***

*omit from the column headed “Brand”:* **Ondansetron AN ODT**

1. **Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[GRP-15983]***

*omit from the column headed “Brand”:* **Ondansetron AN ODT**

1. **Schedule 5, entry for Perindopril, Schedule Equivalent Group GRP-15442**

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Perindopril | GRP-15442 | Tablet containing perindopril erbumine 4 mg | Oral | APO-PerindoprilBTC PerindoprilBlooms the Chemist PerindoprilIdaprex 4Indosyl Mono 4PERISYLPerindo |
|  |  | Tablet containing perindopril arginine 5 mg | Oral | APO-Perindopril ArginineAPX-Perindopril ArginineCoversyl 5mgPREXUM 5 |

1. **Schedule 5, entry for Perindopril, Schedule Equivalent Group GRP-15525**

*substitute:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-15525 | Tablet containing perindopril erbumine 8 mg | Oral | APO-PerindoprilBTC PerindoprilBlooms the Chemist PerindoprilIdaprex 8Indosyl Mono 8PERISYLPerindo |
|  |  | Tablet containing perindopril arginine 10 mg | Oral | APO-Perindopril ArginineAPX-Perindopril ArginineCoversyl 10mgPREXUM 10 |

1. **Schedule 5, entry for Ramipril in the form Capsule 1.25 mg *[GRP-15640]***

*omit from the column headed “Brand”:* **APO-Ramipril**

1. **Schedule 5, entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate)**

*omit from the column headed “Brand”:* **Rizatriptan AN ODT**

1. **Schedule 5, entry for Salbutamol in the form Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 *[GRP-21361]***

*omit from the column headed “Brand”:* **Salbutamol AN**

1. **Schedule 5, after entry for Salbutamol in the form Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 *[GRP-21535]***

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A) | Inhalation | pms-SALBUTAMOL |

1. **Schedule 5, entry for Tenofovir in the form Tablet containing tenofovir disoproxil maleate 300 mg**

*insert in alphabetical order in the column headed “Brand”:* **Tenofovir Disoproxil Viatris**