



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 4 OF 2012

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health and Ageing for the purposes of paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act) and acting in accordance with the Secretary's power under that paragraph of the Act, hereby amend the Poisons Standard 2012 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2012 as set out in Schedule 1 commence on 22 November 2012.

(Signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health and Ageing

Dated this 19th day of November 2012

Schedule 1- Amendments to the Poisons Standard 2012

STANDARD
FOR THE
UNIFORM SCHEDULING
OF
MEDICINES AND POISONS

No. 3

AMENDMENT No. 3

Effective Date – 22 November 2012

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The amendments listed in this document are a result of decisions made by a delegate of the Department of Health and Ageing in November 2012. The basis of these amendments can be found in the 'Reasons for scheduling delegate's final decisions', which can be accessed from the TGA website at www.tga.gov.au/industry/scheduling-decisions.htm.

Further inquiries should be directed to:

The Secretary
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Amendments to the Standard for the Uniform Scheduling of Medicines and Poisons

The Secretary of the Department of Health and Ageing directs that the amendments below be applied to the Standard for the Uniform Scheduling of Medicines and Poisons No. 3 (SUSMP 3) and recommends that these amendments be adopted by the States and Territories with effect from 22 November 2012.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENTS

LORATADINE – Amend entry to read:

LORATADINE in preparations for oral use **except** in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

- (a) in a primary pack containing 5 dosage units or less; and
- (b) labelled with a recommended daily dose not exceeding 10 mg of loratadine.

SCHEDULE 4 – AMENDMENTS

LORATADINE – Amend entry to read:

LORATADINE **except**:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:
 - (i) in a primary pack containing 5 dosage units or less; and
 - (ii) labelled with a recommended daily dose not exceeding 10 mg of loratadine.