Loratadine and desloratadine: proposed advisory statements for medicines

Version 1.0, November 2012
About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.

- The TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.
### Version history

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<th>Description of change</th>
<th>Author</th>
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Historical consultation document
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Loratadine and desloratadine: proposed advisory statements for medicines

Invitation to comment

The TGA is seeking comments from interested parties on the proposed advisory statement for loratadine and desloratadine when included in non prescription medicines for oral administration for inclusion in the Required Advisory Statements for Medicine Label (RASML) document when it is next updated.

Timetable

Document released for consultation on Friday, 9 November 2012

Interested parties should respond by close of business Friday, 7 December 2012

Feedback will be released following consideration of submissions (see 'What will happen')

About the consultation

The proposed advisory statement for loratadine and desloratadine when included in non prescription medicines for oral use would be required on the 'label' of non prescription products containing this medicine. Advisory statements on the label of medicines assist in the quality use of medicines by consumers.

Through the consultation process, the TGA is requesting comment that will help ensure that the proposed advisory statement is appropriate and supports the quality use of medicines for non-prescription products containing loratadine and desloratadine for oral use.

This consultation will contribute to the update of the RASML document.

Note: 'Label' means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods.

Content of submissions

Submissions may address any, or all, of the proposed advisory statement(s) and other identified issues.

In addition, submissions might include:

- Whether or not you support the wording of the advisory statement. If you do not support the wording of the statement you may make suggestions for an alternative acceptable to you.
• An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

How to respond

All submissions should be accompanied by a TGA submission cover sheet. Submissions must include full personal or organizational contact details (including address, telephone number and email).

Electronic submissions are preferred and should be emailed to rasml@tga.gov.au. Please include 'Proposed advisory statements –loratadine and desloratadine' in the subject line of the email.

Alternatively, hard copy submissions may be mailed to:

OTC Medicines Evaluation
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

What will happen

Submissions will be reviewed by the TGA and feedback on submissions will be provided through the TGA's Internet site.

The proposed advisory statements will then be included in the next update of the RASML document.

Confidentiality

All submissions will be placed on the TGA website unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked 'IN CONFIDENCE'. Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA’s website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Enquiries

Enquiries should be directed via email to rasml@tga.gov.au or by telephone to 1800 020 653.
Background

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) sets out the level of control on the availability of medicines and poisons in Australia. The majority of medicines that are included in the SUSMP fall under one of the following classifications.

Schedule 2 – Pharmacy Medicine (available from a pharmacy without a prescription)

Schedule 3 – Pharmacist Only Medicine (available from a pharmacist without a prescription)

Schedule 4 – Prescription Only Medicine (available from a pharmacist with a prescription)

Medicines that are not included in the SUSMP are freely available from both pharmacies and other retail outlets, and are referred to as ‘unscheduled’ medicines. Medicines that are unscheduled or included in Schedule 2 or Schedule 3 of the SUSMP are collectively referred to as ‘non-prescription’ or ‘over-the-counter’ (OTC) medicines.

Consumers rely on information from their health practitioner, pharmacist and medicine ‘label’ in order to use medicines safely and effectively. In the case of non prescription medicines, the label of the medicine contains information and directions for appropriate use, as well as any advisory statements (warnings) that are needed for safe and effective use of the medicines.

The need for a new advisory statement might arise from:

- The registration of a new medicine
- When new risks for currently available medicines have been identified
- A request from external stakeholders and/or expert advisory committees is received
- When a medicine undergoes a change in scheduling, hence reducing the level of control and making it more widely available to consumers for self-selection or available without a prescription

Under these circumstances there may be a need to ensure that appropriate advisory statements are included on the labelling of these medicines to ensure consumers are able to self-select (where applicable) and use these medicines safely and effectively.

Note: ‘Label’ means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods.

Loratadine and desloratadine

In May 2012, the scheduling delegate confirmed a decision to exempt loratadine from scheduling in the SUSMP in divided oral preparations containing 10mg or less or loratadine, in packs containing not more than 5 days supply, for the treatment of seasonal allergic rhinitis in adults and children aged 12 years and over.

In making the decision to ‘down schedule’ this presentation of loratadine from Schedule 2 to unscheduled, the scheduling delegate confirmed the recommendations made by the Advisory Committee on Medicines Scheduling (ACMS) at its February 2012 meeting that the requested exemption from scheduling was acceptable.

Desloratadine is in Schedule 2 in preparations for oral use and has not undergone a scheduling change. However, its similarity to loratadine (as an active metabolite of
loratadine) prompts the same concurrent recommendation for warnings as for loratadine as it is used for the same indications.

Both loratadine and desloratadine are in pregnancy category B1. The Australian regulatory guidelines for OTC medicines (ARGOM) states, in Chapter 5B, that the labels of OTC products that contain active ingredient(s) in any pregnancy category other than category A should include a statement advising consumers who are pregnant or who may become pregnant to check with their doctor or pharmacist before use. Therefore, the TGA has proposed the inclusion of a statement advising consumers who are pregnant or who may become pregnant to check with their doctor or pharmacist before use on labels of OTC products containing loratadine or desloratadine.

Additionally, both loratadine and desloratadine may be excreted in breast milk and their use while breastfeeding is not recommended.

Proposal

Following advice from the Advisory Committee on Non prescription Medicines (ACNM), the TGA proposes the following advisory statement for both loratadine and desloratadine when supplied as a non-prescription medicine under the conditions stated (See Table 1).

Table 1. Proposed advisory statements for loratadine and desloratadine

<table>
<thead>
<tr>
<th>Which Meet The Following Conditions ...</th>
<th>Required advisory statement(s)</th>
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<tr>
<td>When included in non-prescription medicines for oral administration.</td>
<td>If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine</td>
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1 Pregnancy category B1: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.