Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Famciclovir: proposed advisory statements for medicines

Version 1.0, November 2012

TGA Health Safety Regulation

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.
- 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>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, 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 submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	Office of Medicines Authorisation	09/11/2012

Contents

Famciclovir: proposed advisory statements for medicines

Invitation to comment

The TGA is seeking comments from interested parties on the proposed advisory statements for famciclovir when included in non-prescription medicines for oral use for inclusion in the Required Advisory Statements for Medicine Labels (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 statements for famciclovir 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 statements are appropriate and support the quality use of medicines for non-prescription products containing famciclovir 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 statements 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 statement –famciclovir '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/s 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.

Famciclovir

In February 2012, the TGA scheduling delegate decided to include *"Famciclovir for oral use, in divided preparations, containing a total dose of 1500 mg or less of famciclovir for the treatment of herpes labialis (cold sores)"* in Schedule 3 of the *Standard for uniform scheduling of medicines and poisons* (SUSMP), with an implementation date of 1 May 2012.

Famciclovir was previously only included in Schedule 4 of the SUSMP (see above), hence this is a 'down scheduling' of this medicine.

Proposal

Following advice from the Advisory Committee on Non-Prescription Medicines (ACNM), the OTC Medicines Evaluation Section of the TGA proposes the following advisory statements for famciclovir when supplied as a non-prescription medicine under the conditions stated (See Table 1).

Table 1. Proposed advisory statements for famciclovir

Which meet the following conditions ...	Required statement(s)
When included in non-prescription medicines for oral administration	*Do not take [this product / product name] if you are allergic to famciclovir or penciclovir.*
	Do not take [this product / product name] if you have problems with your immune system.
	If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
	Do not take [this product / product name] if you have kidney problems, unless advised by a doctor.
	If you have high blood pressure, heart problems, liver problems, diabetes or other medical conditions, consult your pharmacist or doctor before use.
	If you are taking other medicines regularly, consult your pharmacist or doctor before use.
	If you have symptoms and signs of an infection other than your cold sore, consult your pharmacist or doctor before use.

Therapeutic Goods Administration

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