Australian Government
Department of Health
Therapeutic Goods Administration

Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Menthol

Consultation paper

Version 1.0, March 2021

TGA Health Safety Regulation

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Introduction

Purpose

The Therapeutic Goods Administration (TGA) is seeking comments from interested parties on proposed new advisory statements for labels of over the counter (OTC) and registered complementary medicines containing menthol for dermal use, for inclusion in the Required Advisory Statements for Medicine Labels (RASML). The proposal to include advisory statements for menthol-containing medicines in RASML follows previously implemented requirements for advisory statements on labels of menthol-containing listed medicines.

Background

Advisory statements

Consumers rely on information from their health practitioner, pharmacist and medicine label in order to use medicines safely and effectively. However, the enhanced access and availability of OTC medicines means that consumers may not always receive comprehensive advice from a practitioner or pharmacist.

In the context of self-medication, the medicine label is the primary source of information for the consumer; so the label must contain the directions and advisory statements that are needed for safe and effective use of these medicines.

The TGA Labelling Orders require medicine labels to include 'warning statements' where these apply to the medicines, including any advisory statements specified in the instrument made under subsection 3(5A) of the *Therapeutic Goods Act 1989* ('the Act'), as in force from time to time.

The Required Advisory Statements for Medicine Labels (RASML)

The RASML is registered on the Federal Register of Legislative Instruments under subsection 3(5A) of the Act, as the Therapeutic Goods (Medicines Advisory Statements) Specification 2019 ('the Specification'). The RASML sets out advisory statements that are required to be included on the labels of specified OTC and registered complementary medicines.

The most recent version of the Specification is the Therapeutic Goods (Medicines Advisory Statements) Specification 2019, which comprises RASML No. 5. The transition period for compliance with RASML No. 5 ended on 31 August 2020 and labels must now comply with the advisory statements specified in RASML No. 5.

Finalised advisory statements for menthol would be included in the next version, RASML No. 6. A transition period of 18 months from commencement of the new RASML is provided to allow for existing medicines that do not already comply with new requirements to have their labelling updated.

The advisory statements required by the RASML are designed to inform consumers about specific risks related to the use of medicines that have been identified during development and evaluation of new medicines, or subsequent pharmacovigilance activities, testing, adverse event reports or from other scientific or clinical information.

RASML warnings apply only if the substance is included in the medicine as an active ingredient, unless specified otherwise in the RASML entry. The RASML permits the wording of the actual statements that are included on medicine labels to differ from the wording set out in the RASML, as long as the intent is the same.

Proposed RASML statements for dermal preparations containing menthol

There are currently no warning statements specified in RASML for menthol.

Labels of listed medicines for dermal use containing menthol require the following warning statements, in accordance with the Therapeutic Goods (Permissible Ingredients) Determination:

- *Avoid contact with eyes* (or words to that effect).

If the medicine delivers **more than 1% total menthol** when administered according to the directions for use:

- *If you have sensitive skin, test this product on a small area of skin before applying it to a large area;*
- *If irritation develops, discontinue use.*

If the medicine delivers **more than 5% total menthol** when administered according to the directions for use:

- *Contains a high concentration of menthol, which can cause severe skin irritation.*

These warning statements were included in the Therapeutic Goods (Permissible Ingredients) Determination following evaluation of the available safety and toxicology data and consultation with affected sponsors.

Consistent with the above warnings required for listed medicines, the following entries for menthol are proposed for inclusion in RASML. Separate entries are proposed for patches, for which two of the warning statements are not required.

Proposed RASML entries for menthol

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Menthol *(Entry 1 of 5)*	In dermal preparations containing 1% or less, EXCEPT patches	• Avoid contact with eyes.
Menthol *(Entry 2 of 5)*	In dermal preparations containing more than 1 per cent and up to 5 per cent, EXCEPT patches	• Avoid contact with eyes. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Menthol *(Entry 3 of 5)*	In dermal preparations containing more than 5 per cent, EXCEPT patches	• Avoid contact with eyes. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use. • Contains a high concentration of menthol, which can cause severe skin irritation.
Menthol *(Entry 4 of 5)*	In dermal patches containing more than 1 per cent and up to 5 per cent	• If irritation develops, discontinue use.
Menthol *(Entry 5 of 5)*	In dermal patches containing more than 5 per cent	• If irritation develops, discontinue use. • Contains a high concentration of menthol, which can cause severe skin irritation.

It should be noted that RASML cannot and is not intended to capture all required warning statements for all medicines. Additional warnings may be required for some menthol-containing registered medicines depending on the specific nature of the medicine. These can be considered during evaluation of specific medicine registration applications.

Consultation questions and responses

The TGA is requesting comments that will help ensure that the proposed advisory statements are appropriate and support the quality use of the medicines and that any label changes that would be required for these medicines are made in the most convenient, efficient and cost-effective way.

Submissions must be relevant to warning statements for OTC and registered complementary medicines containing menthol and must be received by the closing date.

Question

Do you support the proposed conditions and wording of the advisory statements?

If there are aspects you do not support, please explain why you do not support them. You may make suggestions for alternative wording or additional statements that you think are suitable.

You may wish to include an assessment of how the proposed changes 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).

To provide your feedback click ‘Make a submission’ on the consultation page and include your response using the free text field and/or file upload function.

All feedback will be considered after the consultation period ends and will be published on the TGA website with your consent.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation Section	March 2021

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Reference/Publication #