Australian Government
Department of Health
Therapeutic Goods Administration

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

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 addition of a proposed new required advisory statement for labels of non-prescription medicines containing more than 1.5 per cent lidocaine (lignocaine) for topical oral use, for inclusion in the Required Advisory Statements for Medicine Labels (RASML) document.

The required advisory statement "Do not use for teething pain in children" is proposed for preparations for topical oral use containing 1.5 per cent or more of lidocaine to ensure that consumers and health professionals are aware that these medicines are not suitable for use for teething in children.

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.

Any changes required to RASML No. 5 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.

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 new RASML statement for lidocaine in preparations for topical oral use

The TGA initiated a safety investigation examining use of lidocaine viscous 2% in infants and young children following the publication of safety review outcomes by Health Canada[1] and the FDA[2]. The reviews from both of these jurisdictions had concluded that there was a link between lidocaine viscous 2% and severe adverse reactions (seizures, severe brain injury, heart problems and death) in this age group and that lidocaine viscous 2% should not be used for teething pain.

In Australia, registered 2% oral viscous lidocaine products already include label warnings not to use for teething in children. The TGA investigation determined that such a warning should be made mandatory via RASML to ensure consistent information across all labels of future products.

The 2% oral viscous lidocaine products contain 2% lidocaine hydrochloride, equal to 1.7% lidocaine base. It is proposed that topical oral preparations containing more than 1.5% lidocaine base be required to include the warning "Do not use for teething pain in children." or words to this effect, as permitted by the RASML (see table below for full RASML entries).

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 lidocaine-containing medicines depending on the specific nature of the medicine. These can be considered during evaluation of specific medicine registration applications.

[1] Health Canada Summary Safety Review August 2016 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/summary-safety-review-viscous-lidocaine-assessing-potential-risk-effects-infants-young-children.html) [D19-5157196]

[2] FDA Drug Safety Communication June 2014 (http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm) [D19-5157443]

Proposed additional RASML entry for medicines containing lidocaine for topical oral use (proposed new entry indicated in red)

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Lidocaine (Lignocaine) *(Entry 1 of ~~3~~4)*	In dermal preparations containing MORE THAN 2 per cent of total local anaesthetic substances	• Do not apply to large areas of the body, except on the advice of a healthcare practitioner. • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Lidocaine (Lignocaine) *(Entry 2 of ~~3~~4)*	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	• If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Lidocaine (Lignocaine) *(Entry 3 of 4)*	In preparations for topical oral use containing more than 1.5 per cent lidocaine.	• Do not use for teething pain in children.
Lidocaine (Lignocaine) *(Entry 3 of ~~3~~4)*	In lozenges	• Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth. • Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.

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 medicines containing lidocaine and must be received by the closing date.

Question

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

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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