Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Draft OTC medicine monograph: Dextromethorphan hydrobromide

Version 1.0, April 2015

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 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 <http://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	OTC Medicines Evaluation/Medicines Authorisation Branch	30/04/2015

Contents

Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral preparations containing dextromethorphan hydrobromide as a single active ingredient when applied for as an OTC new medicine N2 application. Proposed medicines must comply with all aspects of the monograph relevant to their strength and dosage form to qualify for evaluation as an N2 application.

This monograph should be read in conjunction with the document Requirements for OTC new medicine N2 applications.

Active substance

This monograph only applies to medicines containing dextromethorphan hydrobromide (CAS no. 6700-34-1) and excludes preparations containing any other salts and derivatives of dextromethorphan.

Dosage forms and strengths

Acceptable dosage forms and strengths are shown in the table below.

Active substance	Dosage strengths	Dosage form
Dextromethorphan hydrobromide	5 and 10 mg	Lozenge Pastille
	2 mg/mL and 3 mg/mL	Oral liquid

Indications

Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods (ARTG)

Cough suppressant for the temporary relief of non-productive cough.

For lozenges, 'helps soothe sore throats' may be included.

Label indications

Temporary relief of dry cough.

- May be qualified with cough due to common colds.
- Further description of the cough may be included by selecting one or more of the following: non-productive/irritating/stubborn/tickly.

- Relieves dry coughs by suppressing the urge to cough

The following label claims are also acceptable:

- For lozenges:
  - Helps soothe sore throats.
  - Fast/rapid relief from dry cough.
- For oral liquid:
  - Long lasting relief for up to 8 hours (for those with 30 mg single dose every 6-8 hours frequency)

Directions for use

Dosage must be as shown in the tables below.

Lozenges or pastilles:

Dosage strength	Age	Dosage
5 mg	Adults and children 12 years and over	Slowly suck 2 lozenges/pastilles, one after the other, every 2 – 3 hours if necessary. Maximum 24 lozenges/pastilles in 24 hours.
	Children 6 – 11 years*	Slowly suck 1 lozenge/pastille every 2 – 3 hours if necessary. Maximum 12 lozenges/pastilles in 24 hours.
10 mg	Adults and children 12 years and over	Slowly suck 1 – 2 lozenges/pastilles, one after the other, every 4 hours if necessary. Maximum 12 lozenges/pastilles in 24 hours
		OR Slowly suck 1 – 3 lozenges/pastilles, one after the other, every 4 – 6 hours if necessary. Maximum 12 lozenges/pastilles in 24 hours.
	Children 6 – 11 years*	Slowly suck 1 lozenge/pastille every 4 – 6 hours if necessary. Maximum 6 lozenges/pastilles in 24 hours.

* only on the advice of a doctor, pharmacist or nurse practitioner.

Oral liquids:

Dosage strength	Age	Dosage
2 mg/mL	Adults and children 12 years and over	5 – 10 mL (10 – 20 mg) every 4 hours if necessary, maximum 6 doses (120 mg) per day.
		OR 15 mL (30 mg) every 6 – 8 hours if necessary, maximum 4 doses (120 mg) per day.
	Children 6 – 11 years*	2.5 – 5 mL (5 – 10 mg) every 4 hours if necessary, maximum 6 doses (60 mg) per day.
		OR 7.5 mL (15 mg) every 6 – 8 hours if necessary, maximum 4 doses (60 mg) per day.
3 mg/mL	Adults and children 12 years and over	10 mL (30 mg) every 6- 8 hours if necessary, maximum 4 doses (120 mg) per day.
	Children 6 – 11 years*	5 mL (15 mg) every 6 – 8 hours if necessary, maximum 4 doses (60 mg) per day.

*only on the advice of a doctor, pharmacist or nurse practitioner.

Include the following for all dosage forms:

- Do not give to children under 6 years of age.
- If the medicine is not to be indicated for children below 'x' years of age (where 'x' is any age between 6 and 11 years of age), then the label must contain the statement *"Do not give to children under 'x' years of age"* as required by the Required Advisory Statements for Medicine Labels (RASML).

Advisory statements

The following advisory statements are required:

- If coughing persists, consult your doctor or pharmacist.
- Do not take this medicine if you are taking a monoamine oxidase inhibitor (MAOI) or an antidepressant, or have taken the MAOI or antidepressant medicine within the past two weeks.

Labelling

Labelling must comply with all relevant Australian requirements, as detailed in the document Requirements for OTC new medicine N2 applications, including all required warning statements.

Quality requirements

In addition to the quality requirements outlined in the document Requirements for OTC new medicine N2 applications, the following specific requirements apply to dextromethorphan hydrobromide monograph medicines:

Finished product specifications

In addition to other requirements specified in the document Requirements for OTC new medicines N2 applications, the finished product specifications must comply, at a minimum, with the relevant set of requirements below.

The requirements below include relevant BP general monograph/USP General Chapter requirements and TGO78 requirements. References to pharmacopoeial monographs below refer to the current monograph at time of application.

For **lozenges**, the following tests and limits:

- organoleptic properties such as lozenge appearance, odour, taste, etc.
- identification of dextromethorphan hydrobromide
- dextromethorphan hydrobromide content of 92.5 – 107.5%
- uniformity of dosage units (BP)
- any individual degradation products (NMT 0.5%) and total degradation products (NMT 1.0%)
- microbiological quality in compliance with TGO 77.

For **oral solutions**, the tests and limits in the USP monograph *Dextromethorphan Hydrobromide Oral Solution* with the addition of:

- organoleptic properties such as solution appearance, odour, taste, etc.
- content of any preservatives included in the formulation
- any individual degradation products (NMT 0.5%) and total degradation products (NMT 1.0%)
- pH
- microbiological quality in compliance with TGO 77.

Container/measuring device

Dextromethorphan medicines must be sold in containers that comply with Therapeutic Goods Order No 80 - Child Resistant Packaging Requirements for Medicines.

If a measuring device is to be supplied with the medicine, calibrations must be exclusively in metric units and must allow all the doses shown on the labels to be measured accurately. Details of the calibrations on the measuring device must be provided with the submission (a sample may also be requested). Further considerations and requirements regarding measuring devices are detailed in ARGOM Appendix 2: Guidelines on quality aspects of OTC applications, 8. Finished product container.

Therapeutic Goods Administration

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Reference/Publication #