



Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Draft OTC medicine monograph: Bromhexine hydrochloride

Version 1.0, April 2015

TGA Health Safety
Regulation

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- 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>>.

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Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation/Medicines Authorisation Branch	30/04/2015

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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of preparations containing bromhexine hydrochloride 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 preparations that contain bromhexine hydrochloride (CAS no. 611-75-6) as the only active ingredient and excludes preparations containing any other salts and derivatives of bromhexine.

Dosage forms and strengths

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

Active substance	Dosage strengths	Dosage forms
Bromhexine hydrochloride	0.8 mg/mL, and 1.6 mg/mL	Oral liquid
	8 mg	Tablets (conventional immediate release tablets and soluble tablets only)

Indications

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

Mucolytic. Breaks down mucus and helps clear chest congestion.

Label indications

Required label indication is 'Helps clear chest congestion'.

Further description of the relief of chest congestion may be included by selecting one or more of the following:

- Thins/loosens/breaks down mucus to help clear the chest
- Mucolytic

- Helps clear stubborn chest congestion
- Chesty cough

Directions for use

Directions must be as shown in the table below, as relevant.

Dosage strength	Age*	Single dose	Dose interval	Maximum daily dose
0.8 mg/mL oral liquid	Adults and children 12 years and over	10-20 mL (8-16 mg)	Every 8 hours as necessary	3 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)*	10 mL (8 mg)	Every 8 hours as necessary	3 doses
	Do not use in children under 6 years of age.			
1.6 mg/mL oral liquid	Adults and children 12 years and over	5-10 mL (8-16 mg)	Every 8 hours as necessary	3 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)*	5 mL (8 mg)	Every 8 hours as necessary	3 doses
	Do not use in children under 6 years of age.			
8 mg tablet	Adults and children 12 years and over	1 to 2 tablets (8-16 mg)	Every 8 hours as necessary	3 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)*	1 tablet (8 mg)	Every 8 hours as necessary	3 doses
	Do not use in 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 12 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).

Advisory statement

The following advisory statement is also required:

If symptoms persist, consult your doctor or pharmacist.

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 bromhexine hydrochloride monograph medicine.

Finished product specifications

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

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

- tablet appearance
- identity of bromhexine hydrochloride
- for soluble tablets only: disintegration (disintegrate within 3 minutes, using water at 15-25°C as the liquid medium)
- uniformity of dosage units (BP)
- dissolution (900 mL acetate buffer pH 5, paddle at 50 rpm, 70% (Q) after 30 minutes)
- bromhexine hydrochloride content of 92.5 – 107.5%
- individual unspecified impurity (not more than 1.0%) and total impurities (not more than 3.0%)
- microbiological quality in compliance with [Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines](#).

For **oral liquids**, the following tests and limits:

- organoleptic properties (such as appearance, smell, taste etc)
- pH
- identity of bromhexine hydrochloride
- bromhexine hydrochloride content of 90.0 – 110.0%
- individual unspecified impurity (not more than 1.0%) and total impurities (not more than 3.0%)
- content of any preservatives included in the formulation
- microbiological quality in compliance with [Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines](#).

Container/measuring device

Bromhexine hydrochloride 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](#).

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Reference/Publication #