Australian Government
Department of Health
Therapeutic Goods Administration

OTC medicine monograph: Guaifenesin

Version 1.0, December 2014

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>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation/Office of Medicines Authorisation	16/12/2014

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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of a cough expectorant containing guaifenesin 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 guaifenesin (CAS no. 93-14-1).

Dosage forms and strengths

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

Active substance	Dosage strengths	Dosage form *(Excludes modified release dosage forms)*
Guaifenesin	200 mg	Capsules Tablets, chewable tablets, effervescent tablets Powder for oral solution
	10 mg/mL, 13.33 mg/mL, and 20 mg/mL	Oral liquid

Indications

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

Expectorant. Provides symptomatic relief from congested chests and coughs due to the common cold.

Label indications

Required label indication is *"Temporary relief of chesty cough due to common colds."*

The following label indications are also acceptable:

- Expectorant.

- For wet/chesty cough due to common colds.
- Helps loosen phlegm (mucus) due to common colds.
- Temporary relief of chest congestion due to common colds.
- Makes coughs more productive.
- Helps thin bronchial secretions.

Directions for use

Dosages must be as shown in the table below.

Dosage	Single dose	Dose interval	Maximum daily dose
Adults and children 12 years and over	200 to 400 mg	Every 4 to 6 hours when necessary	2400 mg (6 doses in 24 hours)
Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	100 to 200 mg	Every 4 to 6 hours when necessary	1200 mg (6 doses in 24 hours)
Do not use in children under 6 years of age.			

Additional instruction

The following instruction is also required:

If coughing persists, consult your doctor or pharmacist.

Labels

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 guaifenesin monograph medicines:

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.

The requirements below include all relevant BP general monograph/USP General Chapter requirements and TGO 78 requirements. Further references to these are not required.

Reference to the USP monograph below refer to the **current** monograph at the time of application.

1. For **capsules**, the tests and limits in the USP monograph *Guaifenesin Capsules* with the addition of:
   - Capsule appearance.
   - Assay limits 92.5 – 107.5%.
   - Guaifenesin β-isomer NMT 1.5%[1], any other individual impurity NMT 1.0% and total impurities including guaifenesin β-isomer NMT 3.0%.
   - Microbiological quality in compliance with TGO 77.
2. For **tablets (including chewable and effervescent tablets)**, the tests and limits in the USP monograph *Guaifenesin Tablets* with the addition of:
   - Tablet appearance.
   - Assay limits 92.5 – 107.5%.
   - Guaifenesin β-isomer NMT 1.5%[1], any other individual impurity NMT 1.0% and total impurities including guaifenesin β-isomer NMT 3.0%.
   - Microbiological quality in compliance with TGO 77.
3. For **oral solutions**, the tests and limits in the USP monograph *Guaifenesin Oral Solution* with the addition of:
   - Solution appearance.
   - Content of any preservatives included in the formulation.
   - Guaifenesin β-isomer NMT 1.5%[1], any other individual impurity NMT 1.0% and total impurities including guaifenesin β-isomer NMT 3.0%.
   - Microbiological quality in compliance with TGO 77.
4. For **powders for oral solution**, the following tests and limits:
   - Powder appearance and/or solution appearance.
   - Identification (as for USP tablets and capsules).
   - pH of solution between 2.3 and 3.0[2]
   - Uniformity of dosage units if the medicine is packaged in single-unit containers.
   - Assay limits 90.0 – 110.0% LC.
   - Guaifenesin β-isomer NMT 1.5%[1], any other individual impurity NMT 1.0% and total impurities including guaifenesin β-isomer NMT 3.0%.
   - Microbiological quality in compliance with TGO 77.

[1] USP Monographs: Guaifenesin
[2] USP Monographs: Guaifenesin Oral Solution

Container/measuring device

- Guaifenesin 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

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
http://www.tga.gov.au

Reference/Publication #