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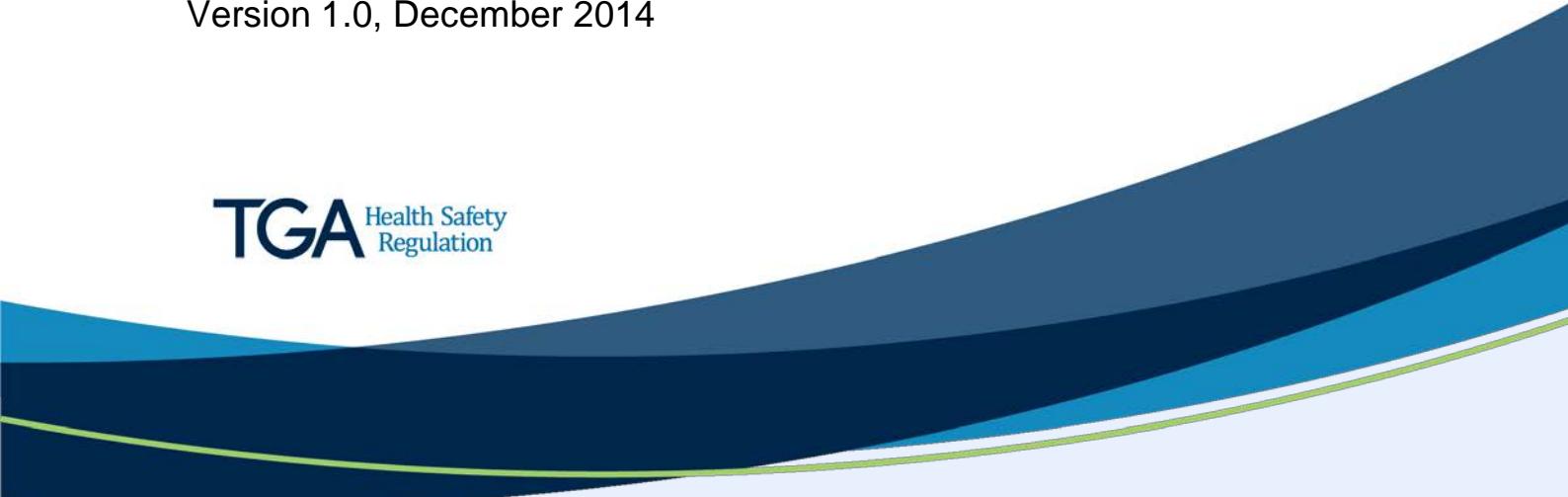
Department of Health

Therapeutic Goods Administration

OTC medicine monograph: Ranitidine hydrochloride

Version 1.0, December 2014

TGA Health Safety
Regulation

A large, stylized graphic element consisting of a thick blue wedge on the right side and a thinner yellow wedge on the left side, both tapering towards the bottom. The background is white.

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>>.

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Version history

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

Contents

Introduction	5
Active substance	5
Dosage forms and strengths	5
Indications	5
Required therapeutic indications for inclusion in the Australian Register of Therapeutic Goods	5
Label indications	5
Directions for use	6
Labelling	6
Quality requirements	7
Finished product specifications	7
Coated tablets	7
Effervescent tablets	7
Oral liquid	7
Container/measuring device	8

Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral medicines containing ranitidine 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 medicines containing ranitidine hydrochloride (CAS no. 66357-59-3) and excludes preparations containing any other salts and derivatives of ranitidine.

Dosage forms and strengths

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

Active substance	Dosage strengths*	Dosage forms (excludes modified release dosage forms)
Ranitidine (as hydrochloride)	150 mg	Coated tablet, effervescent tablet
	300 mg	Coated tablet, effervescent tablet
	15 mg/mL	Oral liquid

* Ranitidine content, equivalent to 167.4 mg, 334.8 mg or 16.74 mg/mL ranitidine hydrochloride, respectively.

Indications

Required therapeutic indications for inclusion in the Australian Register of Therapeutic Goods

Relief of symptoms of gastro-oesophageal reflux.

Label indications

- Symptomatic relief of heartburn
- Reference should also be made, at least once, to relief of 'symptoms of gastro-oesophageal reflux' or 'heartburn due to gastro-oesophageal reflux' or similar.

The following label indications/claims are also acceptable:

- Symptomatic relief of acid indigestion and/or dyspepsia
- 'Works by decreasing the amount of acid made by the stomach', or similar

- 'Long lasting'
- For 150 mg tablet and oral liquid: 'Up to 12 hours relief' and/or '12 hour action'
- For 300 mg tablet: A prominent statement is required on the main panel of the carton label indicating that the medicine is intended for use by patients who routinely require two 150 mg ranitidine tablets for relief of their symptoms. The statement should be presented in such a way that it clearly stands out to prospective purchasers.

Directions for use

Directions are to be as shown in the table below.

Dosage form and strength	Directions
150 mg tablet	Adults and children 12 years and over: Take one tablet at the first sign of symptoms. If symptoms return or persist for more than one hour, take another tablet. Do not take more than 2 tablets in 24 hours. Do not use in children under 12 years.
300 mg tablet	Adults and children 12 years and over: Take one tablet at the first sign of symptoms. Do not take more than 1 tablet in 24 hours. Do not use in children under 12 years.
15 mg/mL oral liquid	Adults and children 12 years and over: Take 10 mL at the first sign of symptoms. If symptoms return or persist for more than one hour, take another 10 mL. Do not take more than 2 doses (20 mL) in 24 hours. Do not use in children under 12 years.

For effervescent tablets, refer to placing the tablet in water and waiting till dissolved.

Directions for coated tablets may refer to taking with a glass of water.

Requirements in relation to measuring devices provided with oral liquid products are included under [Container/measuring device](#).

Labelling

- Labelling must comply with all relevant Australian regulatory requirements, as detailed in the document [Requirements for OTC new medicine N2 applications](#), including all required warning statements.
- In addition to statements required by RASML, the following statement is required:

'If you are pregnant or intend to become pregnant, or are breastfeeding, check with your doctor or pharmacist before using this product.'[#]

[#] This statement will be revised pending a final outcome on a RASML consultation on a pregnancy and breastfeeding warning statement for ranitidine.

- Where 150 and 300 mg strengths of the same brand name are to be marketed, there must be sufficient differentiation between the product name and labelling of the two different

strengths (eg. inclusion of 'Extra strength' in the product name of the 300 mg product and colour differentiation between labelling).

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 ranitidine hydrochloride 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 TG078 requirements. Further reference to these is not required. References to pharmacopoeial monographs below refer to the **current** monograph at time of application.

Coated tablets

The tests and limits in the BP monograph **Ranitidine Tablets** with the addition of:

- tablet appearance
- dissolution (900 mL water, paddle at 50 rpm, 80% (Q) after 45 minutes)¹
- uniformity of dosage units (BP)
- microbiological quality, in compliance with TG0 77

Effervescent tablets

The tests and limits in the BP monograph **Ranitidine Tablets** with the addition of:

- tablet appearance
- disintegration (BP)
- uniformity of dosage units (BP)
- microbiological quality, in compliance with TG0 77

Oral liquid

The tests and limits in the BP or USP monograph **Ranitidine Oral Solution** with the addition of:

- solution appearance
- content of any preservatives included in the formulation
- microbiological quality, in compliance with TG0 77

¹ From *Ranitidine Tablets USP*

Container/measuring device

- If a measuring device is to be supplied with the product, 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 #