



Australian Government

Department of Health

Therapeutic Goods Administration

OTC medicine monograph: Loperamide hydrochloride

Version 1.0, December 2014

TGA Health Safety
Regulation

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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

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Introduction

This OTC medicine monograph outlines the requirements for Australian market authorisation of oral medicines containing loperamide 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 loperamide hydrochloride (CAS no. 34552-83-5) and excludes preparations containing any other salts and derivatives of loperamide.

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)
Loperamide hydrochloride	2 mg	Hard capsules, tablets (uncoated, film coated)

Indications

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

Symptomatic treatment of acute non-specific diarrhoea.

Label indications

The following label indications/claims are acceptable:

- 'Diarrhoea relief'
- 'Effective relief of/from diarrhoea'
- 'Symptomatic relief of/from diarrhoea'
- Reference to 'loose motions'
- 'Relief within 1-3 hours'

Note: Reference to 'fast', 'rapid' or similar is not acceptable.

Directions for use

Adults and children 12 years and over: 2 tablets/capsules initially, followed by 1 tablet after each loose motion, to a maximum of 8 tablets/capsules per day.

Do not give to children under 12 years of age.*

*This is a RASML statement.

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.

Advisory statements

The following advisory statements are required#:

- If the condition persists after two days of treatment, seek medical advice as soon as possible.
- If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.##
- Drink plenty of fluids as fluid and electrolyte depletion may occur with diarrhoea. If dehydration is suspected seek medical attention.
- Do not take if you have a medical condition where constipation should be avoided.
- See your doctor or pharmacist before taking [this medicine/*insert name of medicine*] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing condition affecting the bowel.

The above advisory statements are included in RASML Schedule 2.

This statement will be revised pending a final outcome on a RASML consultation to change the pregnancy and breastfeeding warning statement for loperamide.

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 loperamide hydrochloride monograph medicines:

Manufacture

If the total weight of the tablet or capsule exceeds 100 mg (i.e. active ingredient is less than 2% w/w of the dosage form), the manufacturing process must have been validated on a minimum of two production batches in accordance with the requirements of GMP, prior to submission of the application¹. An assurance that this has been done must be provided with the application.

¹ In accordance with manufacturing process validation requirements for 'microdose' products, as detailed in section 5.2.1 of Appendix 2 of the ARGOM

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.

Tablets

The tests and limits in the USP monograph **Loperamide Hydrochloride Tablets** with the addition of:

- tablet appearance
- tighter limits for loperamide hydrochloride content of 92.5-107.5% (in accordance with TG0 78)
- Loperamide *N*-oxide (NMT 2% wrt loperamide hydrochloride)²
- microbiological quality, in compliance with TG0 77

Capsules

The tests and limits in the BP monograph **Loperamide Capsules**³ with the addition of:

- capsule appearance
- microbiological quality, in compliance with TG0 77

² Use assay method specified for *Loperamide Hydrochloride Capsules BP*, or an alternative equivalent or superior method. The method must be appropriately validated as described in [Requirements for OTC new medicine N2 applications](#).

³ Including dissolution test, with a limit of NLT 70% in 45 min, in accordance with Appendix XII B. Monographs of the British Pharmacopoeia.

Therapeutic Goods Administration

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Reference/Publication #