



Australian Government

Department of Health

Therapeutic Goods Administration

OTC medicine monograph: Topical nasal decongestants

Version 1.0, June 2014

TGA Health Safety
Regulation

A decorative graphic consisting of several overlapping, wavy lines in shades of blue and green, flowing from the left side of the page towards the right, creating a sense of movement and modern design.

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
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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of topical nasal decongestant medicines containing oxymetazoline hydrochloride or xylometazoline 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 substances

This monograph only applies to medicines containing oxymetazoline hydrochloride (CAS No. 2315-02-8) or xylometazoline hydrochloride (CAS No. 1218-35-5) as a single active ingredient and excludes medicines containing any other salts or derivatives of these active ingredients.

Dosage forms and strengths

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

Active substance	Dosage forms	Dosage strengths
Oxymetazoline hydrochloride	Spray, nasal	0.5 mg/mL
Xylometazoline hydrochloride	Spray, nasal Nasal drops	0.5 mg/mL ¹ and 1 mg/mL

¹ For use in children aged 6-11 years only

Indications

Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods

Temporary relief of nasal and sinus congestion due to colds, influenza, sinusitis and allergies.

Label indications

- Label indications should be consistent with the indications above. References to 'runny nose', 'blocked nose', 'stuffy nose', 'flu' and 'hayfever' are also acceptable.
- References to 'fast relief', 'starts to work in minutes', 'relief in minutes' or similar, are acceptable.
- References to 'long lasting', '12 hour relief, or similar, are acceptable for oxymetazoline HCl.
- Reference to 'long lasting', 'lasts up to 10 hours' or similar, are acceptable for xylometazoline HCl.

- Reference to 'temporary' relief must be included at least once on the label in association with the label indications.

Directions for use

Directions for use and advisory statements, as detailed below, are required on the carton and container labels. However, for small containers where label space may be limited, abbreviation or omission of some information may be appropriate. As much information as possible should be included on the container label while still maintaining readability.

Dosage

Active /strength	Dosage instructions
Oxymetazoline hydrochloride	Adults and children 6 years and over: 2-3 sprays into each nostril every 10-12 hours, as required. Do not exceed 2 doses in 24 hours. Use in children from 6-11 years only on the advice of a doctor, pharmacist or nurse practitioner. Do not use in children under 6 years of age.
Xylometazoline hydrochloride 0.5 mg/mL	Children 6-11 years, only on the advice of a doctor, pharmacist or nurse practitioner: 2 sprays or 2-3 drops into each nostril every 8-10 hours, as required. Do not exceed 3 doses in 24 hours. Do not use in children under 6 years of age.
Xylometazoline hydrochloride 1 mg/mL	Adults and children 12 years and over: 1 spray or 2-3 drops into each nostril every 8-10 hours, as required. Do not exceed 3 doses in 24 hours. Do not use in children under 12 years of age.

Additional instructions

- Include instruction to blow the nose before administering.
- Instructions regarding use of the pump and other safety statements may be included as appropriate.
- The statement 'This product should be used by only one person. Sharing may spread infection' may be included.

Advisory statements

The following advisory statements are required:

- 'Do not use for more than three days at a time unless advised by a doctor or pharmacist.'
- 'If congestion persists, consult your doctor or pharmacist.'
- 'Frequent or prolonged use may cause nasal congestion to recur or worsen.'

- 'If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this product.' (only required on the primary (outer) pack label)

Note: This monograph currently includes all required advisory statements for oxymetazoline hydrochloride and xylometazoline hydrochloride, including those specified in the 'Australian regulatory guidelines for OTC medicines' (ARGOM) and the 'Required advisory statements for medicine labels' (RASML).

Labelling

Labelling must comply with all relevant Australian regulatory requirements, as detailed in the document [Requirements for OTC new medicine N2 applications](#).

Note: Labelling for metered-dose sprays should include the minimum number of sprays in the container, in accordance with the definition for 'quantity of the goods' in 2(1) of TGO69 (this refers to number of 'doses', but 'sprays' is most appropriate). Fill volume should also be included.

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 topical nasal decongestant 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. Further reference to these is not required. References to pharmacopoeial monographs below refer to the **current** monograph at time of application.

Oxymetazoline hydrochloride spray

The tests and limits in the USP monograph **Oxymetazoline Hydrochloride Nasal Solution** with the addition of:

- solution appearance
- delivered dose uniformity, in accordance with USP General Chapter <601>. Where the label does not specify a dose per actuation, the 'label claim' referred to in the USP test should be calculated from the volume delivered per actuation and the concentration of the solution
- BP impurity A (see BP Medicinal and Pharmaceutical Substances monograph for Oxymetazoline Hydrochloride; NMT 1.5%); other individual impurities (NMT 1.0%); and total impurities (NMT 3.0%)
- content of any preservatives included in the formulation
- microbiological quality, in compliance with TGO 77

Xylometazoline hydrochloride spray

The tests and limits in the USP monograph **Xylometazoline Hydrochloride Nasal Solution** with the addition of:

- solution appearance
- delivered dose uniformity, in accordance with USP General Chapter <601>. Where the label does not specify a dose per actuation, the 'label claim' referred to in the USP test should be calculated from the nominal volume delivered per actuation and the concentration of the solution
- BP impurity A (see BP Medicinal and Pharmaceutical Substances monograph for Xylometazoline Hydrochloride; NMT 3.0%¹); other individual impurities (NMT 1.0%); and total impurities (NMT 3.0%)
- content of any preservatives included in the formulation
- microbiological quality, in compliance with TGO 77

Xylometazoline hydrochloride drops

The tests and limits in the USP monograph **Xylometazoline Hydrochloride Nasal Solution** with the addition of:

- solution appearance
- BP impurity A (see BP Medicinal and Pharmaceutical Substances monograph for Xylometazoline Hydrochloride; NMT 3.0%¹); other individual impurities (NMT 1.0%); and total impurities (NMT 3.0%)
- content of any preservatives included in the formulation
- microbiological quality, in compliance with TGO 77

or

the tests and limits in the BP monograph **Xylometazoline Nasal Drops** with the addition of:

- solution appearance
- other individual impurities (NMT 1.0%); and total impurities (NMT 3.0%)
- content of any preservatives included in the formulation
- microbiological quality, in compliance with TGO 77

¹ Consistent with the limit for this impurity (specified as *N*-(2-Aminoethyl)-4-*tert*-butyl-2,6-xylylacetamide) in Xylometazoline Nasal Drops BP.

Container

Nasal sprays are to be in metered dose spray containers with target volume per actuation as follows:

Oxymetazoline hydrochloride 0.5 mg/mL:	50 – 100 µl per spray
Xylometazoline hydrochloride 0.5 mg/mL:	60 – 80 µl per spray
Xylometazoline hydrochloride 1 mg/mL:	130 – 150 µl per spray

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