



Australian Government

Department of Health

Therapeutic Goods Administration

OTC medicine monograph: Topical imidazole antifungals for dermal use - clotrimazole and miconazole nitrate

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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>>.

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Version history

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Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of topical imidazole antifungal medicines for dermal use containing clotrimazole or miconazole nitrate as a single active ingredient when applied for as an OTC New Medicine N2 application. It does not apply to preparations for oral mucosal or intra-vaginal use. 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 either clotrimazole (CAS no. 23593-75-1) or miconazole nitrate (CAS no. 22832-87-7) as a single active ingredient and excludes preparations containing any salts and derivatives of clotrimazole or miconazole nitrate.

Dosage forms and strengths

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

Active substance	Dosage strengths	Dosage forms
Clotrimazole	10 mg/g	Cream
	10 mg/mL	Solution
Miconazole nitrate	20 mg/g	Cream
		Powder

Indications

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

Required indications are shown in the following table:

Medicine Schedule*	ARTG indications
When included in SUSMP Schedule 2*	<p>Topical treatment of fungal skin infections such as tinea or ringworm (eg. tinea pedis, tinea corporis or tinea cruris#; Pityriasis versicolor; and candidal infections (eg. external genital thrush**, thrush-infected nappy rash**).</p> <p>For miconazole nitrate creams only, the indication 'seborrhoeic dermatitis associated with Pityrosporum organisms, when present on the face and body (except the scalp)' may be added in addition to the above required indication.</p> <p>#Jock itch indication can only be included for non-alcoholic based formulation.</p> <p>**External genital thrush and thrush-infected nappy rash may be added as examples of candidal infections for creams only.</p>
When excluded from the SUSMP*	Topical treatment of tinea pedis (athlete's foot).

*Refer to the current *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*.

Label indications

Required label indications are shown in the table below:

Medicine Schedule*	Label indications
When included in SUSMP Schedule 2*	<ul style="list-style-type: none"> • Treatment of fungal skin infections such as tinea or ringworm, athlete's foot, jock itch#, pityriasis versicolor and candidal skin infections including external genital thrush** and thrush-infected nappy rash**. • For miconazole nitrate creams only, the claim 'mild seborrhoeic dermatitis when present on the face and body (except scalp)' may be added in addition to the above acceptable label indications. <p>#The claim for jock itch can only be included for non-alcoholic based formulations.</p> <p>**The claims 'including external genital thrush and thrush-infected nappy rash' may be added for creams only.</p>
When excluded from the SUSMP*	Antifungal treatment of athlete's foot (tinea pedis).

*Refer to the current *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*.

Terms should be exactly as specified above. The term 'fungal nappy rash' may be used as an alternate to 'thrush-infected nappy rash'.

In addition to the above label indications, the following label claims may be included for those medicines in SUSMP Schedule 2:

- Broad spectrum antifungal.
- Treats common fungal and candidal skin infections.

Directions for use

Clotrimazole cream and solution

Clean and dry the affected area thoroughly. Apply a thin layer of cream/solution to the affected area and rub in gently, two to three times daily. Continue treatment for 2 weeks after symptoms disappear to avoid recurrence. Regular application is essential for successful treatment.

For spray solutions, include instructions on how to prime and use the spray.

Miconazole nitrate cream

Clean and dry the affected area thoroughly. Apply a thin layer of cream to the affected area and rub in gently twice daily. Continue treatment for 2 weeks after symptoms disappear to avoid recurrence. Regular application is essential for successful treatment.

Miconazole nitrate powder

Clean and dry the affected area thoroughly. Apply a thin layer of powder onto the affected area twice daily. The powder may also be dusted/applied inside clothing/footwear that is in contact with the affected area, for example socks, shoes or underwear, to keep the skin dry. Continue treatment for 2 weeks after symptoms disappear to avoid recurrence. Regular application is essential for successful treatment.

Additional instructions

The following instructions are also required:

Dosage form	Warnings
Cream	For external use only. Avoid contact with the eyes.
Powder	For external use only. Avoid contact with the eyes. Avoid inhalation.
Solution	For external use only. Avoid contact with the eyes. For alcohol-based formulation, include: Avoid contact with sensitive areas such as the eyes, ears, nose, lips, genitalia and inflamed or broken skin. Avoid inhalation.

It is acceptable to include the following additional directions for use:

- Cleanse with a soap alternative as soap may irritate the skin.
- When indicated for nappy rash: Avoid use of baby wipes to cleanse the affected area as they may irritate the skin.

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 clotrimazole or miconazole nitrate monograph medicines:

Finished product specifications

In addition to other requirements specified in the document [Requirements for OTC new medicines 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 the time of application.

Clotrimazole cream

The tests and limits in the **BP monograph *Clotrimazole cream*** with the addition of:

- cream appearance;
- individual unspecified impurities (NMT 1.0%); and total impurities (NMT 3.0%)¹;
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

or

The test and limits in the **USP monograph *Clotrimazole Cream*** with the addition of:

- cream appearance;
- 2-Chlorotritanol (NMT 1.0%), individual unspecified impurities (NMT 1.0%) and total impurities (NMT 3.0%)²;
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

Clotrimazole solution

The tests and limits in the **USP monograph *Clotrimazole Topical Solution*** with the addition of:

- solution appearance

¹ In addition to impurities specified in the BP monograph

² The USP monograph includes no impurity limits

- 2-Chlorotritanol (NMT 1.0%), individual unspecified impurities (NMT 1.0%) and total impurities (NMT 3.0%)²;
- content of any preservatives included in the formulation;
- microbiological quality in compliance with TGO 77.

Miconazole nitrate cream

The tests and limits in the **BP monograph** *Miconazole Cream* with the addition of:

- cream appearance;
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

or

The tests and limits in the **USP monograph** *Miconazole Nitrate Cream* with the addition of:

- cream appearance;
- any individual impurity (NMT 0.25%) and total impurities (NMT 0.5%)³;
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

Miconazole nitrate powder

The tests and limits in the **USP monograph** *Miconazole Nitrate Topical Powder* with the addition of:

- powder appearance;
- any individual impurity (NMT 0.25%); and total impurities (NMT 0.5%)³, and
- microbiological quality in compliance with TGO 77.

³ In accordance with the BP monograph *Miconazole Cream*

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>