PRODUCT INFORMATION- DAKTARIN CREAM, POWDER, SPRAY POWDER, TINCTURE

1 NAME OF THE MEDICINE

Miconazole- cream, powder, spray powder

Miconazole Nitrate- tincture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

DAKTARIN Cream contains miconazole nitrate 2%w/w.
Excipients: butylated hydroxyanisole, liquid paraffin, ethylene glycol, apricot kernel oil PEG-6 esters, tefose 63, purified water and benzoic acid as a preservative.

DAKTARIN Powder contains miconazole nitrate 2%
Exipeints: silica-colloidal anhydrous, zinc oxide and talc. It is a white homogenous powder.

DAKTARIN Spray Powder contains miconazole nitrate 2%
Excipients: ethanol, propane, butane, sorbitan sesquioleate, stearalkonium hectorite and talc-purified.

DAKTARIN Tincture contains miconazole base 2%
Excipients: propylene glycol, ethanol, and acrylates copolymer.

3 PHARMACEUTICAL FORM

Daktarin Cream: water miscible white cream with a pH of 2.6-3.6

Daktarin Powder: white homogenous powder Daktarin Powder Spray: smooth, non-gritty, off-white alcoholic paste with a characteristic odour

Daktarin Tincture: colourless to faintly yellow solution with a pH of 5.5

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Daktarin Cream, Lotion, Powder and Spray Powder are indicated for the topical treatment of the following fungal infections:

- Cutaneous candidiasis (moniliasis), caused by Candida albicans;
- Tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T.mentagrophytes and Epidermophyton floccosum.
- Tinea versicolour caused by Pityrosporum orbicular (Malassezia furfur).

Daktarin Tincture is indicated for the topical treatment of tinea unguium caused by Candida albicans, Trichophyton rubrum, T.mentagrophytes and Epidermophyton floccosum.

4.2 DOSE AND METHOD OF ADMINISTRATION

A thin layer of DAKTARIN Cream sufficient to cover the affected area should be applied and rubbed well into the skin. In patients with tinea pedis, tinea cruris, tinea corporis and cutaneous candidiasis, the cream or lotion should be applied twice daily, and in patients with tinea versicolour, once daily.

DAKTARIN Powder should be applied directly to the lesions and also dusted inside articles of clothing in contact with the affected areas. This should be carried out twice daily.

The DAKTARIN Spray Powder can must be well shaken before use. It should be held about 15cm from the area to be treated and a thin layer is applied twice daily.

Treatment must be continued, without interruption until the lesions have completely healed. Candida infections should be treated for 2 weeks and dermatophyte infections for one month.

Nail Infections: before treatment commences, the nail should be cut as short as possible. A thin layer of DAKTARIN Tincture should be applied to the affected nail, the area around it and if possible under it twice daily. After the infected nail has come off, the treatment should be continued without interruption until a new nail has grown and the lesions are completely cured (usually for at least 2 months). If the nail falls off during the course of treatment, this is due to the infection not to DAKTARIN Tincture. Before reapplying the product, clean the nail of any product buildup with acetone based nail polish remover

NOTE - To improve the therapeutic results of treatment, certain hygienic measures must be taken such as washing the infected regions every day, disinfecting and frequently changing stockings and shoes.

4.3 CONTRAINDICATIONS

DAKTARIN Cream, Powder, Spray Powder and Tincture are contraindicated in the following situations:

- Patients with known hypersensitivity to the active ingredient and/or any of the other excipients in these presentations;
- Patients with known hypersensitivity to similar antifungal agents such as ketoconazole.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Not all strains of a particular organism may be susceptible to miconazole.

As with other drugs of this class, prolonged use may result in overgrowth of non-susceptible micro-organisms.

Intractable candidiasis may be the presenting symptom of unrecognised diabetes. Appropriate tests should therefore be performed in patients not responding to treatment.

Discontinue DAKTARIN if sensitisation or irritation is reported during use.

Daktarin must not come into contact with the eyes.

Tincture is an alcoholic solution and should not be applied to open lesions.

Avoid spraying DAKTARIN Spray Powder in the eyes.

DAKTARIN powder contains talc. Avoid inhalation of the powder to prevent irritation of airways, In particular, when treating infants and children, careful application should be used to prevent inhalation by the child.

Use in the elderly

No data available.

Paediatric use

No data available

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions occur very rarely. In patients on oral anticoagulants, such as warfarin, caution should be exercised and the anticoagulant effect should be monitored. The effects and side effects of some other drugs (e.g., oral hypoglycemics and phenytoin), when co-administered with miconazole, can be increased and caution should be exercised.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy – Pregnancy Category A

Although no problems have been documented, despite assumed extensive use of this drug in pregnancy, safety for use during pregnancy has not been established through prospective studies.

Use in lactation

It is not known whether miconazole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DAKTARIN is administered to a mother who is breast-feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration'.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse drug reactions reported among 834 patients who received miconazole 2% cream and/or placebo cream base in 21 double-blind clinical trials are presented in Table 1 below. Included in

the table are all adverse events considered to be related to study drug. A dash indicates that the adverse reaction was not reported by patients in the specified treatment group.

Table 1: Adverse drug reactions reported by patients in either treatment group in 21 double-blind clinical trials of miconazole 2% cream versus placebo.

System Organ Class Adverse drug reaction	Miconazole 2% Cream (n=426), %	Placebo Cream Base (n=408), %
Overall adverse drug reactions	1.9	1.2
Skin and subcutaneous tissue disorders		
Skin burning sensation	0.2	0.7
Skin inflammation	0.2	--
Skin hypopigmentation	0.2	--
General disorders and administration site conditions		
Application site irritation	0.7	0.5
Application site burning	0.2	0.2
Application site pruritus	0.2	--
Application site reaction NOS	0.2	--
Application site warmth	0.2	--

Note: Individual patients may have reported more than a single event.

Postmarketing Data

Adverse drug reactions from spontaneous reports during the worldwide post-marketing experience with DAKTARIN that meet threshold criteria are included in Table 2. The adverse drug reactions are ranked by frequency, using the following convention:

Very common	≥1/10
Common	≥1/100 and <1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000, <1/1,000
Very rare	<1/10,000, including isolated reports

The frequencies provided below reflect reporting rates for adverse drug reactions from spontaneous reports, and do not represent more precise estimates of incidence that might be obtained in clinical or epidemiological studies.

Immune System Disorders	
Very rare	angioneurotic edema, anaphylactic reaction, Hypersensitivity
Skin and Subcutaneous Tissue Disorders	
Very rare	urticaria, contact dermatitis, rash, erythema urticaria, contact dermatitis, rash, erythema
General disorders	
Very rare	application site reactions, including application, site irritation

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at: https://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Treatment of overdose is symptomatic and supportive. In the event of overdosage, or if accidentally swallowed, contact the Poisons Information Centre on 13 11 26 in Australia or 0800 764 766 in New Zealand.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Miconazole exhibits antifungal activity against Candida albicans, the dermatophytes - Trichophyton rubrum, T.mentagrophytes, Epidermophyton floccosum and Pityrosporum orbicular (Malassezia furfur). Miconazole penetrates the fungal cell wall, alters cellular membranes, and interferes with intracellular enzymes and biosynthesis of ergosterol.

Clinical Trials

Refer to section 4.8 for clinical trials.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Systemic absorption of miconazole is limited, with a bioavailability of less than 1% following application of miconazole. Plasma concentrations of miconazole and/or its metabolites were measurable 24 and 48 hours after application.

Systemic absorption has also been demonstrated after repeated application of miconazole to infants with diaper dermatitis. Plasma levels of miconazole were undetectable or low in all infants.

Distribution

Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%)

Excretion

The small amount of miconazole that is absorbed is eliminated predominantly in feces as both unchanged drug and metabolites over a four-day post-administration period. Smaller amounts of unchanged drug and metabolites also appear in urine.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 - Qualitative and quantitative composition

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine. Refer to section 4.5: Interactions with other medicines and other forms of interactions.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

DAKTARIN Cream tubes of 15g, 30g & 70g with `Instructions for Use' leaflet.

DAKTARIN Powder in a 30g "puffer" pack.

DAKTARIN Tincture in a 30mL bottle with brush.

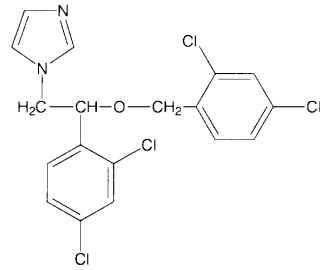
DAKTARIN Spray Powder in a 100g pressurised can.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



Chemical Name: Miconazole is 1-[2,4-dichloro-beta-(2,4-dichlorobenzyloxy)phenethyl]imidazole derivative and is a synthetic 1-phenethylimidazole derivative.

Miconazole nitrate is 1-[2,4-dichloro-beta-(2,4-dichlorobenzyloxy)phenethyl]imidazole nitrate, and is a synthetic 1-phenethylimidazole derivative.

Miconazole: A white, microcrystalline powder, practically insoluble in water but soluble in ethanol (10%).

Miconazole Nitrate: A white, microcrystalline powder, very slightly soluble in water and in ether; soluble in 140 parts of ethanol (96%), and slightly soluble in chloroform.

Chemical formula:

Miconazole: C18H14Cl4 N2O

Miconazole nitrate: C18H14Cl4N2O.HNO3

MW:

Miconazole: 416.14

Miconazole nitrate: 479.16

CAS number

Miconazole: 22916-47-8

Miconazole nitrate: 22832-87-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Pharmacy Medicine (S2)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

18 March 2010

10 DATE OF REVISION

December 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reformatted product information