Daktarin®

(Miconazole Nitrate)

Cream for topical use

NAME OF THE MEDICINAL PRODUCT

DAKTARIN® Cream

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20 mg of the active substance miconazole nitrate

PHARMACEUTICAL FORM

White homogenous cream for topical use.

CLINICAL INFORMATION

Indications

Skin infections due to dermatophytes or yeasts, and other fungi such as: Tinea capitis, corporis, manuum, barbae, cruris, pedis (athlete's foot). Since DAKTARIN has an antibacterial effect on gram positive bacteria, it may be used in mycoses secondarily infected with such bacteria (e.g. in napkin dermatitis).

Dosage and Administration

Apply some cream to the lesions twice daily. Rub the cream into the skin with your finger until it has fully penetrated the skin. The duration of therapy varies from 2 to 6 weeks depending on the localization and the severity of the lesion. Treatment should be continued at least one week after disappearance of all signs and symptoms.

Contraindications

DAKTARIN Cream is contraindicated in individuals with a known hypersensitivity to miconazole, another ingredient of the formulation, or other imidazole derivatives.

Warnings and Precautions

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with DAKTARIN Cream and with other miconazole topical formulations (see Adverse Reactions). If a reaction suggesting sensitivity or irritation should occur, the treatment should be discontinued. DAKTARIN Cream must not come into contact with the eyes.

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.

Pregnancy and Breast-feeding

Pregnancy

DAKTARIN Cream applied topically is minimally absorbed into the systemic circulation (bioavailability < 1%). Although there is no evidence that miconazole is embryotoxic or teratogenic in animals, potential hazards of prescribing DAKTARIN Cream during pregnancy should always be weighed against the expected therapeutic benefits.

Breast-feeding

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation

Effects on Ability to Drive and Use Machines

Not applicable

Adverse Reactions

Clinical Trial Data:

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 reactions reported by patients in either treatment group in 21 double-blind clinical trials of miconazole nitrate 2% cream versus placebo

System/Organ Class Adverse Reaction	Miconazole Nitrate 2% Cream (n= 426), %	Placebo Cream Base (n=408), %
Overall adverse drug reactions	1.9	1.2
Skin and subcutaneous Issue 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:

In addition to the adverse reactions reported during clinical studies and listed above, the following adverse reactions have been reported during postmarketing experience. The frequencies are provided according to the following convention:

Very common ≥1/10; Common ≥1/100 and <1/10; Uncommon ≥1/1000 and <1/100; Rare ≥1/10000 and <1/1000; Very rare < 1/10000, including isolated reports.

Adverse reactions are presented by frequency category based on spontaneous reporting rates, when known.

Table 2: Adverse Reactions Identified During Post-Marketing Experience with DAKTARIN Cream by Frequency Category Estimated from Spontaneous Reporting Rates

Immune system disorders	
Very rare	Anaphylactic reaction, hypersensitivity
Skin and subcutaneous tissue disorders	
Very rare	Angioedema, urticaria, contact dermatitis, rash, erythema, pruritus, skin burning sensation
General disorders and administration site conditions	
Very rare	Application site reactions, including application site irritation

Below adverse reactions are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

Table 3: Adverse Reactions Identified During Postmarketing Experience with Daktarin by Frequency Category Estimated from Clinical Trials or Epidemiologic Studies of Daktarin

Immune system disorders	
Not known	Anaphylactic reaction, hypersensitivity
Skin and subcutaneous tissue disorders	
Uncommon	Skin burning sensation
Not known	Angioedema, urticaria, contact dermatitis, rash, erythema, pruritus
General disorders and administration site conditions	
Uncommon	Application site reactions, including application site irritation

Overdose

Symptoms and signs

Topical use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Treatment

Accidental ingestion: DAKTARIN Cream is intended for topical use, not for oral use. Should accidental oral ingestion of large quantities occur, use appropriate supportive care.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Antifungal for dermatological / topical uses, imidazole derivative, ATC code: D01AC02.

Mechanism of action:

Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis.

Pharmacodynamic effects:

Usually, miconazole acts very rapidly on pruritus, which frequently accompanies dermatophyte and yeast infections. This symptomatic improvement is seen before the first signs of healing are observed. Miconazole has also been proven to be effective in secondarily infected mycoses.

Microbiology:

Miconazole combines an antifungal activity against the common dermatophytes, yeasts and various other fungi with an antibacterial activity against certain gram-positive bacilli and cocci.

Pharmacokinetic Properties

Absorption:

Miconazole remains in the skin after topical application for up to 4 days. Systemic absorption of miconazole is limited, with a bioavailability of less than 1% following topical 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%).

Metabolism and 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.

NON-CLINICAL INFORMATION

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

PHARMACEUTICAL INFORMATION

Shelf Life

Observe expiry date on the outer pack.

Special Precautions for Storage

As prescribed by the physician.
Do not store above 30°C.
Protect from light.
Keep out of reach of children.

ہدایات :

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پہ نہ رکھیں۔
دوا کو روشنی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

Nature and Contents of Container

Daktarin 20mg/g (miconazole nitrate) is supplied in tube of 10g.

REVISION DATE

February 2024

Manufactured by:
Aspin Pharma (Pvt) Ltd.,
Plot No. 10 & 25, Sector No. 20, Korangi Industrial Area,
Karachi-74900, Pakistan. www.aspin.com.pk

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