SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Daktarin 2% Cream.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole nitrate 2% w/w
(Each gram of cream contains 20mg of miconazole nitrate).

Excipients: Also contains 2 mg/g of Benzoic acid (E210) and 0.052 mg/g of Butylated hydroxyanisole (E320).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
White homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mycotic infections of the skin and nails and superinfections due to Gram-positive bacteria.

4.2 Posology and method of administration

Route of administration: Cutaneous use.

Recommended dosage:

For all ages:

Fungal infections of the skin: Apply some cream to the lesions two times daily. Rub the cream into the skin with your finger until it has fully penetrated. If the powder is used with the cream, a once daily application of both formulations is recommended. The duration of therapy varies from 2 to 6 weeks depending on the localisation and the severity of the lesion. Treatment should be continued at least one week after disappearance of all signs and symptoms.

Nail infections: Apply the cream once or twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

4.3 Contraindications

Hypersensitivity to the active substance, other imidazole derivatives or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Daktarin Cream must not come into contact with the mucosa of the eyes.

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 hypersensitivity or irritation should occur, the treatment should be discontinued.

This medicine contains 2 mg of Benzoic acid (E210) per gram. Benzoic acid may cause local irritation. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine also contains 0.052 mg/g of Butylated hydroxyanisole (E320) which may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

4.6 Fertility, pregnancy and lactation

Pregnancy
In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

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.

4.7 Effects on ability to drive and use machines

Daktarin Cream has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Adverse drug reactions reported among 834 patients who received miconazole nitrate 2% cream (n=426) and/or placebo cream base (n=408) in 21 double-blind clinical trials are presented in Table 1 below. Moreover, adverse drug reactions from spontaneous reports during the worldwide post-marketing experience with Daktarin that meet threshold criteria are included in Table 1. 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 and <1/1,000
Very rare <1/10,000, including isolated reports

Adverse reactions obtained from clinical studies and post-marketing surveillance are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

Table 1: Adverse reactions reported in clinical trials and post-marketing experience

System Organ Class	**Adverse Reactions**	
	Frequency Category	
	Uncommon (≥1/1,000 to <1/100)	**Not known**
Immune System Disorders		Anaphylactic reaction Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Skin burning sensation Skin inflammation Skin hypopigmentation	Angioedema Urticaria Contact dermatitis Rash Erythema Pruritus
General Disorders and Administration Site Conditions	Application site irritation Application site burning Application site pruritus Application site reaction NOS Application site warmth	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

Treatment
Daktarin cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative) *ATC code:* D01A C02.
Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

5.2 Pharmacokinetic properties

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.
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 faeces as both unchanged drug and metabolites.

5.3 Preclinical safety data

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

PEG-6, PEG-32 and glycol stearate
Oleoyl macroglycerides
Liquid paraffin
Benzoic acid (E210)
Butylated hydroxyanisole (E320)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube inner lined with heat polymerised epoxy-phenol resin with a white polypropylene cap containing 15 g, 30 g or 70 g of cream, or aluminium tube inner lined with heat polymerised epoxy-phenol resin with a high density polyethylene cap containing 5 g of cream.
Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited

50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0307

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/10/2024

10 DATE OF REVISION OF THE TEXT

11/10/2024