Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Daktarin 2% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains miconazole nitrate 2% w/w (20 mg/g).

Excipients with known effect:
Butylated hydroxyanisole: 0.052 mg per gram of cream
Benzoic acid: 2 mg per gram of cream

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
White homogenous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of fungal infections of the skin and secondary infections due to Gram-positive bacteria.

4.2 Posology and method of administration

For cutaneous administration.

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 severity of the lesion. Treatment should continue for at least one week after the disappearance of all signs and symptoms.

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

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole topical formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Daktarin Cream must not come into contact with the mucosa of the eyes.

This medicine contains 2 mg/g of Benzoic acid (E210). 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 0.05 mg/g of Butylated hydroxyanisole (E320) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucosa membranes.

Miconazole administered systemically is known to inhibit CYP3A4/2C9, which can lead to prolonged effects of warfarin or other vitamin K antagonists. While systemic absorption is limited with topical formulations, the concomitant use of Daktarin 2% w/w Cream or other vitamin K antagonists should be done with caution and the anticoagulant effect should be carefully monitored and titrated. Patients should be advised of the symptoms of bleeding events and to immediately stop treatment with miconazole and seek medical advice should they occur (see section 4.5).

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 warfarin or other vitamin K antagonists, caution should be exercised and anticoagulant effect should be monitored.

The effects and side effects of some other drugs (e.g. oral hypoglycaemics and phenytoin), when co-administered with miconazole, can be increased and caution should be exercised.

4.6 Fertility, pregnancy and lactation

Pregnancy
Daktarin Cream applied topically is minimally absorbed into the 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 effects.

Lactation
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

Not applicable.

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 from spontaneous reports 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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

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

Treatment
Accidental ingestion: 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 a synthetic imidazole agent with a broad spectrum of activity against pathogenic fungi (including yeasts and dermatophytes) and gram-positive bacteria (*Staphylococcus* and *Streptococcus* spp).

5.2 Pharmacokinetic properties

Absorption: Miconazole remains in the skin after cutaneous application for up to 4 days. Systemic absorption of miconazole is limited, with a bioavailability of less than 1% following cutaneous 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 nappy rash. 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 faeces 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

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

Macrogol 6 stearate (PEG 6)
Macrogol 32 stearate (PEG 32)
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

Internally lacquered collapsible aluminum tube containing 15 g or 30 g of cream with a white polypropylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements,
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA23490/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 March 1988

Date of last renewal: 31 March 2008

10 DATE OF REVISION OF THE TEXT

November 2025