Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Daktarin 2% w/w Cutaneous Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains miconazole nitrate 2% w/w (20mg/g)
Each gram of cutaneous powder contains 20mg of Miconazole Nitrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous powder
White free-flowing powder.

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. The powder may be applied separately or with the cream to skin lesions.

4.2 Posology and method of administration

For cutaneous administration.
Apply powder once or twice daily to affected areas until the lesions have completely healed.

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 Powder must not come into contact with the mucosa of 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.

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 cutaneous application (See Section 5.2 Pharmacokinetic properties), clinically relevant interactions are unlikely to occur. However, in patients on oral anticoagulants, such as warfarin, 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 Powder 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 Powder during pregnancy should always be weighed against the expected therapeutic benefits.

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 frequencies, 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@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
Daktarin Powder is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

Accidental inhalation of talc-containing powder: Massive accidental aspiration of Daktarin powder may cause impaction blockage of airways. Respiratory arrest should be treated with intensive supportive therapy and oxygen. If respiration is compromised, endotracheal intubation, removal of impacted material, and assisted breathing should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative)
ATC code: D01A C02.

Miconazole 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: 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 to 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

Talc (E553b)
Zinc oxide
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

White polyethylene bottle containing 20 g of powder with white polypropylene dredging applicator and cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

JNTL Consumer Health I (Ireland) Limited
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Block 5
High Street
Tallaght
Dublin 24
D24 YK8N
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8 MARKETING AUTHORISATION NUMBER

PA23490/028/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 31 March 2008

10 DATE OF REVISION OF THE TEXT

May 2024