

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Daktarin Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Daktarin Powder contains miconazole nitrate 2.0% w/w.

(Each gram of powder contains 20mg of miconazole nitrate)

For the full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Cutaneous powder

White powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Daktarin powder is for cutaneous administration.

Adults

Twice daily application of powder to the lesions, treatment being prolonged for some 10 days after all lesions have disappeared to prevent relapse.

Elderly and children

As for adults.

4.3 Contraindications

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

The powder should not be recommended for the treatment of infections of the hair and nails.

4.4. Special warnings and precautions for use

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Daktarin Powder and with other miconazole topical formulations (see Adverse Reactions). 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 the airways. In particular, when treating infants and children, careful application should be used to prevent inhalation by the child.

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 Powder and warfarin 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. Interactions 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.

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 Powder 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 $\geq 1/10$
- Common $\geq 1/100$ and $< 1/10$
- Uncommon $\geq 1/1,000$ and $< 1/100$
- Rare $\geq 1/10,000$ 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 in clinical trials and post-marketing experience

| System Organ Class | Adverse Reactions | |
|-------------------------|---|---|
| | Frequency Category | |
| | Uncommon ($\geq 1/1,000$ 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 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 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

Talc
Zinc Oxide
Colloidal Anhydrous Silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High-density polyethylene bottle with a polypropylene dredger-cap and screw-cap containing 20 g or 30 g* of powder

*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 15513/0308

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 July 2008

10 DATE OF REVISION OF THE TEXT

03/10/2025