

Long-form EI (for more information, see rule 41 of the PAGB professional code)

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Daktarin 2% Cream Product Information:

Presentation: White homogeneous cream containing miconazole nitrate 2% w/w.

Uses: Treatment of mycotic infections of the skin and nails and superinfections due to Gram-positive bacteria.

Dosage: Fungal infections of the skin: Apply some cream to the lesions twice 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 be continued at least one week after disappearance of all signs and symptoms. Nail infections: Apply once or twice daily to the lesions and continue for 10 days after all lesions have disappeared to prevent relapse. **Contraindications:** Hypersensitivity to the active substance(s), other imidazole derivatives or to any of the excipients listed in SPC section 6.1.

Precautions: Daktarin 2% Cream must not come into contact with the mucosa of the eyes. If a reaction suggesting sensitivity or irritation should occur, the treatment should be discontinued. Benzoic acid (E210) is mildly irritant to the skin, eyes and mucous membranes. Butylated hydroxyanisole (E320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. In patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

Fertility, pregnancy and breast-feeding: Use with caution. Consult a doctor prior to use.

Side-effects: *Uncommon:* skin burning sensation, skin inflammation, skin hypopigmentation, application site irritation, application site burning, application site pruritus, application site reaction NOS, application site warmth. *Frequency not known:* anaphylactic reaction, hypersensitivity, angioedema, urticaria, contact dermatitis, rash, erythema and pruritus.

RRP (ex-VAT): 15g tube, £4.96.

Legal category: P.

PL holder: McNeil Products Ltd, 50- 100 Holmers Farm Way, High Wycombe, HP12 4EG.

PL numbers: 15513/0307.

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