

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 Aktiv Cream (miconazole nitrate) Product Information:

Presentation:

White cream containing miconazole nitrate 2% w/w.

Uses:

Treatment of athlete's foot.

Dosage:

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.

Contraindications:

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

Precautions:

Discontinue treatment if a reaction suggesting hypersensitivity or irritation should occur. Must not come into contact with the mucosa of the eyes. Contains 2 mg of Benzoic acid (E210) per gram which may cause local irritation and may increase jaundice in newborn babies (up to 4 weeks old). 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.

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.

Not Known: Anaphylactic reaction, hypersensitivity, angioedema, urticaria, contact dermatitis, rash, erythema, pruritus.

RRP (ex-VAT): 30g tube, £7.24; 15g tube, £4.79

Legal category: GSL.

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

PL numbers: 15513/0304.

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