

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Daktarin Intensiv cream (Ketoconazole) Product Information:

Presentation:

White cream containing ketoconazole 2% w/w. Excipients with known effect: propylene glycol, stearyl alcohol, cetyl alcohol.

Indication:

For the treatment of the following mycotic infections of the skin: tinea pedis and tinea cruris.

Dosage and Administration:

For use in adults. For topical administration. For tinea pedis and tinea cruris, Daktarin Intensiv cream should be applied to the affected and immediate surrounding areas once or twice daily. The usual duration of treatment is 2 - 4 weeks for tinea cruris and 4 – 6 weeks for tinea pedis. Treatment should be continued, until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after four weeks of treatment.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

Precautions:

Not for ophthalmic use. After stopping a prolonged treatment with topical corticosteroids, it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Daktarin Intensiv cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks. This medicine contains cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Also contains propylene glycol which may cause skin irritation.

Fertility, pregnancy and lactation:

There are no known risks associated with the use of Daktarin Intensiv cream in pregnancy or lactation. Consult a doctor prior to use.

Side-effects:

Common: skin burning sensation, application site erythema, pruritus.

Uncommon: application site reaction, bleeding, discomfort, dryness, inflammation, irritation, paraesthesia. bullous eruption, contact dermatitis, rash, skin exfoliation, sticky skin, hypersensitivity.

Not known frequency: urticaria.

RRP (ex-VAT): 15g tube, £5.74

Legal category: GSL

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

PL Numbers: 15513/0181

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