

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 Gold 2% Cream (ketoconazole) - Product Information:

Presentation:

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

Uses:

For the treatment of the following mycotic infections of the skin: tinea pedis (athlete's foot), tinea cruris (dhobie itch) and candidal intertrigo (sweat rash).

Dosage:

For use in adults. For topical administration. For tinea cruris, candidal intertrigo and tinea pedis, Daktarin Gold 2% 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, 2 – 4 weeks for candidal intertrigo 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 4 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 Gold 2% 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 Gold 2% cream in pregnancy or lactation. Consult a doctor prior to use.

Side-effects:

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

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

Not known frequency: urticaria.

RRP (ex VAT): 15g tube, £5.74

Legal category: P

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

PL numbers: 15513/0184

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