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 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 to 4 weeks for tinea cruris, 2 to 4 weeks for candidal intertrigo and 4 to 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 to 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.

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:

<u>Common</u>: skin burning sensation, application site erythema, application site pruritus. <u>Uncommon</u>: hypersensitivity, bullous eruption, contact dermatitis, rash, skin exfoliation, sticky skin, application site bleeding, application site discomfort, application site dryness, application site inflammation, application site irritation, application site paraesthesia, application site reaction.

Not known: urticaria.

RRP (ex VAT): 15g tube, £7.54

Legal category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe,

Buckinghamshire, HP12 4EG. PL Number(s): PL 15513/0184 Date of prep: 02 NOV 2020.