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 Powder (Miconazole Nitrate) Product Information:

# **Presentation:**

White powder containing miconazole nitrate 2% w/w.

# Indication:

Treatment of mycotic infections of skin and superinfections due to Gram positive bacteria. **Dosage and Administration:** 

Apply twice daily to the lesions and continue for 10 days after all lesions have disappeared to prevent relapse. For cutaneous use.

### **Contraindications:**

Hypersensitivity to the active substance(s), other imidazole derivatives or to any of the excipients listed in SPC section 6.1. Not recommended for the treatment of infections of the hair and nails.

### **Precautions:**

Discontinue if a reaction suggesting hypersensitivity or irritation occurs. Daktarin Powder must not come into contact with the mucosa of the eyes. This product contains talc. Avoid inhalation of the powder to prevent irritation of the airways. In particular, when treating infants and children, careful application should be used to prevent inhalation by the child.

# **Pregnancy and Breast-feeding:**

Use with caution. Consult a doctor prior to use.

### Side-effects:

<u>Uncommon</u>: Skin burning sensation, skin inflammation, skin hypopigmentation, application site reactions including irritation, burning, pruritus and warmth.

<u>Frequency not known</u>: Anaphylactic reaction, hypersensitivity, angioedema, urticaria, contact dermatitis, rash, erythema, pruritus. See SPC for further details.

**RRP (ex VAT):** 20g tub, £6.00

### Legal category: P

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

PL numbers: 15513/0308

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