

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 Spray Powder (Miconazole Nitrate) Product Information:

Presentation:

Cutaneous spray powder containing miconazole nitrate 0.16% w/w.

Indication:

For the treatment and prevention of athlete's foot.

Dosage and Administration:

Apply to infected area twice daily until lesions are healed. 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 to be used on hair infections, nail infections or broken skin.

Precautions:

The spray should be kept away from the eyes and mucous membranes. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. 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. This medicine contains 255 mg (10% w/w) ethanol in each gram powder. It may cause burning sensation on damaged skin. Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

Pregnancy and Breast-feeding:

Use with caution. Consult a doctor prior to use.

Side-effects:

Very rare: anaphylactic reaction, hypersensitivity, angioedema, urticaria, contact dermatitis, rash, erythema, pruritus, skin burning sensation.

Rare: application site reactions including application site irritation. See SPC for further details.

RRP (ex-VAT): 100g can, £6.71

Legal category: GSL

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

PL numbers: 15513/0306

Date of Preparation: 22 Feb 2023