

**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 Oral Gel (MICONAZOLE 20mg per gram) Product Information**

### **Presentation:**

White gel with an orange taste containing 20mg miconazole per gram.

### **Indication:**

Oral treatment of fungal (e.g. Candida) infections of the oropharynx in adults and paediatric patients 4 months and older.

### **Dosage and Administration:**

For topical treatment of the oropharynx. Infants: 4 – 24 months: 1.25 ml ( $\frac{1}{4}$  measuring spoon of gel), applied four times a day after meals. Each dose should be divided into smaller portions and the gel should be applied to the affected area(s) with a clean finger. The gel should not be applied to the back of the throat due to possible choking. The gel should not be swallowed immediately but kept in the mouth as long as possible. Adults and children 2 years of age and older: 2.5ml ( $\frac{1}{2}$  measuring spoon of gel), applied four times a day after meals. The gel should not be swallowed immediately but kept in the mouth as long as possible. The treatment should be continued for at least a week after the symptoms have disappeared. For oral candidosis, dental prostheses should be removed at night and brushed with the gel.

### **Contraindications:**

Hypersensitivity to the active substance(s), other imidazole derivatives or to any of the excipients listed in SPC section 6.1. Infants less than 4 months of age or in those whose swallowing reflex is not yet sufficiently developed. Liver dysfunction. Daktarin Oral Gel should not be given concurrently with substrates known to prolong the QT-interval, e.g., astemizole, cisapride, dofetilide, mizolastine, pimozone, quinidine, sertindole, terfenadine, ergot alkaloids, triazolam, oral midazolam, or HMG-CoA reductase inhibitors such as simvastatin and lovastatin.

### **Precautions:**

If the concomitant use of Daktarin and drugs such as anticoagulants like warfarin, is planned, the anticoagulant effect should be carefully monitored and titrated. Miconazole is systemically absorbed and is known to inhibit CYP2C9 and CYP3A4 which can lead to prolonged effects of warfarin. Bleeding events, some with fatal outcomes have been reported with concurrent use of miconazole oral gel and warfarin. Patients should be advised that if they experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit, to stop treatment with miconazole and seek medical advice. It is advisable to monitor miconazole and phenytoin levels, if these two drugs are used concomitantly. Serious skin reactions (e.g. Toxic epidermal necrolysis and Stevens-Johnson syndrome) have been reported in patients receiving Daktarin Oral Gel (see section 4.8). It is recommended to discontinue

the use of Daktarin Oral Gel upon the first appearance of a skin rash. In patients using certain oral hypoglycaemics such as sulphonylureas, an enhanced therapeutic effect leading to hypoglycaemia may occur during concomitant treatment with miconazole and appropriate measures should be considered. Caution should be used when Daktarin is taken concomitantly with drugs subject to metabolism by CYP3A4 and CYP2C9. The lower age limit should be increased to 5 – 6 months of age for infants who are pre-term, or infants exhibiting slow neuromuscular development. Choking in infants and young children - Particularly aged 4 months – 2 years, caution is required, to ensure that the gel does not obstruct the throat. Hence, the gel should not be applied to the back of the throat. Observe the patient for possible choking. This medicine contains 0.00785 g of alcohol (ethanol) in each gram of oral gel. The amount in 1 g is equivalent to less than 1 mL beer or 1 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

**Fertility, Pregnancy and Lactation:**

Daktarin Oral Gel should be avoided in pregnant women if possible. Consult a doctor prior to use. The potential hazards should be balanced against the possible benefits. Caution in nursing mothers.

**Side effects:**

Increases in INR and bleeding events such as epistaxis, contusion, haematuria, melaena, haematemesis, haematoma and haemorrhages have been reported in patients treated with oral anticoagulants such as warfarin in association with miconazole oral gel. Some events had fatal outcomes.

Common: dry mouth, nausea, oral discomfort, vomiting, regurgitation and abnormal product taste.

Uncommon: dysgeusia.

Unknown frequency: anaphylactic reaction, hypersensitivity, choking, diarrhoea, stomatitis, tongue discolouration, hepatitis, angioedema, toxic epidermal necrolysis, Stevens-Johnson syndrome, urticaria and rash. Acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms. See SPC for details.

**RRP (ex-VAT):** 80g tube £ 4.79

**Legal category:** POM.

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

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