

Only for the use of medical professionals

Micoral® oral gel

Miconazole

Description

Micoral® oral gel is the preparation of Miconazole. It is a synthetic imidazole which exhibits broad spectrum activity against pathogenic dermatophytes, including Trichophyton species and yeasts including Candida species, Cryptococcus neoformans, Coccidioides immitis and Paracoccidioides brasiliensis as well as range of gram-positive cocci and bacilli. It acts by inhibiting membrane sterol synthesis and interfering with the permeability of the fungal cell membranes.

Indications

Micoral® oral gel is indicated in the treatment and prevention of fungal infections of the oropharynx and gastrointestinal tract and of superinfections due to gram positive bacteria, including oral candidosis and denture stomatitis. Also indicated in prophylactic management of patients at high risk from opportunistic fungal infection.

Dosage and administration

For oral administration: Dosage is based on 15 mg/ kg/ day.

Infants under 2 years: Half spoonful (2.5 ml) of gel twice daily.

Children aged 2-6 years: One spoonful (5 ml) of gel twice daily.

Children aged 6 years and over: One spoonful (5 ml) of gel four times daily.

Adult patients: One or two spoonfuls (5-10 ml) of gel four times daily.

In case of localized lesions of the mouth, a small amount of gel may be applied directly to the affected area with a clean finger, 2-4 times a day. For best results Micoral® oral gel should be kept in contact with the affected area as long as possible. The treatment should be continued for up to two days after symptoms have cleared. For oral candidiasis, dental prosthesis should be removed at night and brushed with the gel.

Elderly patients: Same as adult dose.

Use in pregnancy and lactation

There is no information concerning the safety of Miconazole oral gel during pregnancy. So Miconazole oral gel should be avoided in pregnant women if possible.

The potential hazards should be balanced against the possible benefits. As many drugs are excreted in human milk, caution should be exercised when Miconazole is administered to a nursing woman.

Side effects

Occasionally, nausea and vomiting, diarrhoea with long term use, rarely allergic reactions, isolated reports of hepatitis.

Contraindications

Miconazole is contraindicated in patients with known hypersensitivity to the active ingredient.

Precautions

If the concomitant use of Miconazole and Anticoagulant is considered, the anti-coagulant effect should be monitored and titrated. Miconazole and Phenytoin level should also be

monitored when used concomitantly. In infants and young children, caution must be taken to ensure that the gel does not obstruct the throat. Hence, the gel should not be applied to the back of the throat and the full dose should be divided into smaller portions.

Drug Interactions

Miconazole can inhibit the metabolism of drugs metabolized by the Cytochrome P450-3A and -2C9 families. Miconazole oral gel should not be used during treatment with cisapride, trizolam, oral midazolam, mizolastine, quinidine, simvastatin and lovastatin.

Overdosages

In general Miconazole is not highly toxic. Accidental overdose may cause vomiting and diarrhoea.

Pharmaceutical precautions

Store in a cool and dry place.

Presentation

Micoral® oral gel: Each gm contains Miconazole Base USP 20 mg.

Package quantities

Micoral® oral gel: Tube of 15 gm.

® Registered Trade Mark



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