

MycO OG Oral Gel

Miconazole BP 2% w/w

Presentation

MycO OG oral gel: Each gram gel contains 20 mg Miconazole BP.

Description

The active ingredient, Miconazole, is a synthetic imidazole anti-fungal agent with a broad spectrum of activity against pathogenic fungi (including yeast and dermatophytes) and gram-positive bacteria (*Staphylococcus* and *Streptococcus spp*). It may act by interfering with the permeability of the fungal cell membranes. When administered orally, Miconazole is incompletely absorbed from the gastrointestinal tract, peak plasma levels of about 1 µg per ml have been achieved after a dose of 1 gm per day. Miconazole is inactivated in the body and 10-20% of an oral dose is excreted in the urine, mainly as metabolites, within 6 days. About 50% of an oral dose may be excreted unchanged in the faeces.

Indications

Oral treatment and prevention of fungal infections of the oropharynx and gastrointestinal tract, and of super infections due to Gram-positive bacteria.

Dosage & Administration

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

Adults: 1-2 tea-spoonfuls of gel four times daily.

Children aged 6 years and over: One tea-spoonful of gel four times daily.

Children aged 2-6 years: One tea-spoonful of gel twice daily.

Infants under 2 years: Half tea-spoonful of gel twice daily.

For localized lesions of the mouth, a small amount of gel may be applied directly to the affected area with a clean finger.

For topical treatment of the oropharynx, the gel should be kept in the mouth for as long as possible.

Treatment should be continued for up to 2 days after the symptoms have cleared.

For oral candidiasis, dental prostheses should be removed at night and brushed with the gel.

Side Effects

Occasionally, nausea and vomiting have been reported, and with long term treatment, diarrhoea. In rare instances, allergic reactions have been reported. There are isolated reports of hepatitis, for which the causal relationship with Miconazole has not been established.

Contraindications

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

Precaution & Warnings

If the concomitant use of Miconazole and anticoagulants is envisaged, the anticoagulant effect should be carefully monitored and titrated. It is advisable to monitor Miconazole and Phenytoin levels, if they are used concomitantly. Particularly in infants and young children, 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 and the full dose should be divided into smaller portions. Observe the patient for possible choking.

Overdose

In general, Miconazole is not highly toxic. In the event of accidental over dosage, vomiting and diarrhoea may occur.

Drug Interactions

Miconazole can inhibit the metabolism of drugs metabolised by the Cytochrome P450-3A and -2C9 families. This can result in an increase or prolongation of their effects, including side effects. Miconazole Oral Gel should not be used during treatment with the following drugs: Terfenadine, Astemizole, Mizolastine, Cisapride, Triazolam, oral Midazolam, Dofetilide, Quinidine, Pimozide, CYP3A4 metabolised HMG-CoA reductase inhibitors such as Simvastatin and Lovastatin.

Pregnancy & Lactation

In animals, Miconazole has shown no teratogenic effects but is foetotoxic at high oral doses. The significance of this to man is unknown. However, as with other imidazoles, Miconazole Oral Gel should be avoided in pregnant women if possible. The potential hazards should be balanced against the possible benefits. It is not known whether Miconazole is excreted in human milk. Caution should be exercised when prescribing Miconazole Oral Gel to nursing mothers.

Storage

Store in a cool and dry place, protected from light.

How Supplied

MycO OG oral gel: Each tube containing 15 gm gel.



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