

# Oroconazol<sup>®</sup> Oral Gel



Miconazole 2%

## Presentation

Oroconazol<sup>®</sup> Oral Gel: Each gram gel contains Miconazole BP 20 mg.

## Description

Miconazole is a synthetic imidazole antifungal agent with a broad spectrum of activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain gram positive bacilli and cocci. It acts by inhibiting ergosterol biosynthesis in fungi and change in the lipid components in the membrane, resulting in fungal cell necrosis.

## Indications and uses

Oral treatment and prevention of fungal infections of the oropharynx and gastrointestinal tract and of superinfections due to Gram-positive bacteria, including oral candidiasis and denture stomatitis.

## Dosage and administration

For oral use

Dosage is based on 15 mg/kg/day

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

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

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

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

For localised 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 been 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 diarrhea. In rare instances allergic reactions have been reported.

## Contraindications

The drug is contraindicated in individuals with a history of sensitivity reactions to Miconazole or any of the components of the preparation.

## Precautions

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

## Use in pregnancy and lactation

During pregnancy, this medication should be used only when clearly needed. It is not known whether this drug passes into breast milk.

## Drug interaction

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 terfenadine, astemizole, mizolastine, triazolam, oral midazolam, quinidine, simvastatin and lovastatin.

## Overdosage

In general, Miconazole is not highly toxic. In the event of accidental overdosage, vomiting and diarrhea may occur.

## Storage

Do not store above 30<sup>o</sup> C. Keep out of the reach of children.

## Commercial pack

Oroconazol<sup>®</sup> Oral Gel: Each tube contains 15 gram of Miconazole oral gel.

Manufactured by



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