

# Candoral®

Miconazole 2% w/w

Oral Gel

## Description

Candoral® Oral Gel is the preparation of Miconazole. It 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). Its activity is based on the inhibition of the ergosterol (principle component of fungi cell membrane) biosynthesis in fungi and the change in the composition of the lipid components in the membrane, resulting in fungal cell necrosis.

## Indication

Candoral® Oral Gel is indicated to treat and prevent of fungal infections of the oropharynx (e.g. oral candidiasis in babies and oral candidiasis in other age groups), gastrointestinal tract, nipple & breast of lactating mother and of super infections due to Gram-positive bacteria. Also indicated in prophylactic management of patients at high risk from opportunistic fungal infection.

## Dosage & Administration

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

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

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

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

*Adults:* 1-2 tea-spoonfuls (5-10 ml) of gel four times daily.

For 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 Candoral® Oral Gel should be kept in contact with the affected area 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.

## Adverse Effects

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

## Contraindication

Candoral® Oral Gel is contraindicated in patients with known hypersensitivity to the active drug.

## Precaution

If the concomitant use of Miconazole and anticoagulants is considered, 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.

## Overdose

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

## Drug Interaction

Miconazole can inhibit the metabolism of drugs which are 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 terfenadine, astemizole, mizolastine, cisapride, triazolam, oral midazolam, dofetilide, quinidine, pimozide, simvastatin and lovastatin.

## Use In Pregnancy & Lactation

In animals, Miconazole has shown no teratogenic effects but is foetotoxic at high oral doses. The significance of this to human is unknown. However, as with other imidazoles, Miconazole 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 to nursing mothers.

## Pharmaceutical Precautions

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

## Commercial Pack

Candoral® Oral Gel: Each pack has a tube containing 15 gm oral gel and a spoon. Each gram contains Miconazole USP 20 mg.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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