

# Unigal<sup>®</sup> Oral gel

Miconazole BP 2% w/w

**Description:** The active ingredient, Miconazole, is an 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).

**Mode of action:** At low concentrations, it interacts with fungal cytochrome P450 which results in inhibition of demethylation step in the biosynthesis of ergosterol. At high concentrations, miconazole interacts with membrane lipids causing direct membrane damage which results in leakage of fungal cell constituents. It appears that fungistatic effects results from the inhibition of the barrier function of the membrane.

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

**Indications:** Oral treatment and prevention of fungal infections of the oropharynx (mouth and throat) and gastrointestinal tract (stomach and intestines), 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 aged from 1 month to 2 years:* Half tea-spoonful of gel twice daily.

*Neonates:* 1 ml 2-4 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 4 times daily for 5-7 days. 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.

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

**Side effects:** Occasionally, nausea and vomiting and with long term treatment, diarrhea have been reported. In rare instances, allergic reactions have been reported.

**Use in 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.

**Precautions:** 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. So, the full dose should be divided into smaller portions. Observe the patients for possible choking.

**Drug interactions:** Miconazole can inhibit the metabolism of drugs metabolized 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 be used during treatment with the following drugs: terfenadine, astemizole, mizolastine, cisapride, trizolam, oral midazolam, dofetilide, quinidine, pimozide, CYP3A4 metabolized HMG-CoA reductase inhibitors such as simvastatin and lovastatin.

**Over dosage:** In general, Miconazole is not highly toxic. In the event accidental overdosage, vomiting and diarrhoea may occur.

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

**Packaging: Unigal<sup>®</sup> Oral Gel:** Each pack has a tube containing 15 gm gel and a spoon.



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