Gelora® Oral Gel™

Miconazole

COMPOSITION
Gelora® Oral Gel: Each gram gel contains Miconazole BP 20 mg.

PHARMACOLOGY
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 level of about 1 µg per ml has been achieved after a dose of 1 gm per day.

INDICATION
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: 1 tea-spoonful of gel four times daily
Children aged 2-6 years: 1 tea-spoonful of gel twice daily
Infants under 2 years: 1/2 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 candidasis, dental prostheses should be removed at night and brushed with the gel.

ADVERSE EFFECTS
Occasionally, nausea and vomiting and with long term treatment, diarrhoea have been reported. 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.

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

PRECAUTION & WARNING
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 patient for possible choking.

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 metabolised by the Cytochrome P450-3A and CYP-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.

USE IN PREGNANCY AND LACTATION
In animals, Miconazole has shown no teratogenic effects but is foetotoxic at high oral doses. The significance of this to male 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
Use only with the suggestion of registered physician. Protect from light, store below 30°C. Keep out of reach of the children.

HOW SUPPLIED
Gelora® Oral Gel: Each pack has a tube containing 15 gm gel

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH