MICOSINA

MICONAZOLE BP

Compositions:
Each gram gel contains Miconazole BP 20 mg.

Pharmacology:
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.

Dosage And Administration:
For oral administration: The usual dose is 15 mg/kg/day in divided doses. Adults: 1-2 tea-spoonfuls of gel 4 times daily. Children aged 6 years and over: 1 tea-spoonful of gel 4 times daily. Children aged 2-6 years: 1 tea-spoonful of gel twice daily. 1 month - 2 years: ½ tea-spoonful of gel twice daily. Localized lesions of mouth: Smear small amount on affected area with clean finger 4 times daily for 5-7 days.

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

Warning And Precaution:
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.

Side Effects:
Nausea, vomiting, diarrhoea (with long-term treatment); rarely allergic reactions; isolated reports of hepatitis.

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 medicines metabolised by cytochrome 3A4 and 2C9 enzyme systems. This can result in an increase and/or prolongation of the 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.

Overdosage:
Emergency medical attention is required in case of overdose.

Storage:
Store at controlled temperature of 20-25°C. Protect from light and keep out of the reach of children.

Packing:
Each tube contains 15 gm oral gel.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.