

# Mizol

## Miconazole

### COMPOSITION:

**Mizol** Oral Gel: Each gram gel contains Miconazole Nitrate USP equivalent to Miconazole 20 mg.

### PHARMACOLOGY:

**Mizol** (Miconazole) is a broad-spectrum antimycotic which offers a high antifungal activity against dermatophytes, yeasts and other phyco-asco and Adelomycetes, with a potent antibacterial activity against Gram-positive *bacilli* and *cocci*. **Mizol** proved to be markedly effective in secondary infected mycoses, which under other treatments were resistant or reappeared. **Mizol** oral gel does not stain skin or clothes.

### INDICATION:

**Mizol** oral gel is indicated in the 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. Also indicated in prophylactic management of patients at high risk from opportunistic fungal infection.

### DOSAGE AND ADMINISTRATION:

For oral administration: Dosage is based on 15 mg/ kg/ day. *Infants under 2 years*: Half spoonful (2.5 ml) of gel twice daily. *Children aged 2-6 years*: One spoonful (5 ml) of gel twice daily. *Children aged 6 years and over*: One spoonful (5 ml) of gel four times daily. *Adult patients*: One or two spoonfuls (5-10 ml) of gel four times daily. In case of 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 **Mizol** oral gel should be kept in contact with the affected area as long as possible. The treatment should be continued for up to two days after symptoms have cleared. For oral *candidiasis*, dental prosthesis should be removed at night and brushed with the gel. *Elderly patients*: Same as adult dose.

### CONTRAINDICATION:

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

### SIDE EFFECT:

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

### USE IN PREGNANCY AND LACTATION:

There is no information concerning the safety of Miconazole oral gel during pregnancy. So Miconazole oral gel should be avoided in pregnant women if possible. The potential hazards should be balanced against the possible benefits. As many drugs are excreted in human milk, caution should be exercised when Miconazole is administered to a nursing woman.

### 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 cisapride, trizolam, oral midazolam, mizolastine, quinidine, simvastatin and lovastatin.

### OVERDOSAGE:

In general Miconazole is not highly toxic. Accidental overdosage may cause vomiting and diarrhoea.

### PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

### HOW SUPPLIED:

**Mizol** Oral Gel: Each tube contains 15 gm oral gel.

**Manufactured by:**



**MEDICON Pharmaceuticals Ltd.**  
Mirpur, Dhaka, Bangladesh