

Composition:

Mycon Oral Gel: Each gram gel contains Miconazole BP 20 mg.

Pharmacology:

Miconazole, a synthetic imidazole derivative, possesses an antifungal activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain gram-positive bacilli and cocci. Miconazole selectively blocks ergosterol synthesis by inhibiting demethylation of lanosterol and thereby cause fungal cell death.

Indications:

Mycon Oral Gel is indicated for the prevention & treatment of fungal infections of mouth, throat, stomach & intestine.

Dosage & administration:

Oral Candidiasis:

Neonate: 1/5 tea-spoonful 2-4 times daily

Child 1 month - 23 months: 1/4 tea-spoonful 4 times daily Child 2 years - Adult: 1/2 tea-spoonful 4 times daily

Intestinal Candidiasis:

Child 4 months - Adult: 5 mg/kg (body weight) 4 times daily

Direction of use:

For treating localised areas of infection in the mouth, a small amount of Mycon Oral Gel may be applied directly to the affected area. For best results in the treatment of oral lesions, Mycon Oral Gel must be kept in contact with the affected areas as long as possible. Treatment is generally continued for 7 days after the symptoms disappear. Application of the gel is preferably done after meals.

Contraindications:

Miconazole Oral Gel is contraindicated in patients with known hypersensitivity to any of its components and in patients with liver dysfunction.

Side effects:

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

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.

Use in pregnancy and lactation:

Although there is no evidence that Miconazole is embryotoxic or teratogenic in animals, potential hazards of prescribing these medicines during pregnancy should always be weighed against the expected therapeutic benefits. There are no data available on the excretion of Miconazole in human milk; therefore caution should be exercised when breastfeeding women are using Miconazole.

Overdose:

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

Storage

Store below 30°C, protect from light & Keep in a dry place. Keep out of the reach of children.

Packing:

Mycon Oral Gel: Each pack has a tube containing 15 g.

