

Symbiotrin

Miconazole USP

COMPOSITION

Each gram of gel contains Miconazole USP 20 mg.

PHARMACOLOGY

Symbiotrin (Miconazole) is a synthetic broad spectrum anti-fungal agent and acts against pathogenic fungi including yeast and dermatophytes and gram-positive bacteria (*Staphylococcus* and *Streptococcus spp*). It acts by inhibiting membrane sterol synthesis and interfering with the permeability of the fungal cell membranes.

INDICATIONS

It is indicated in the treatment and prevention of fungal infections of the oropharynx and gastrointestinal tract.

DOSAGE AND ADMINISTRATION

Oropharyngeal candidiasis

Infants 4-24 month: 1.25 ml (1/4 measuring spoon) of gel, applied 4 times day after meals.

Adult and children 2 years of age and older: 2.5 ml (1/2 measuring spoon) of gel, applied 4 times a day after meals.

Gastrointestinal tract candidiasis

Infants (4 months of age or above), children and adults who have difficulty swallowing tablets: 20 mg per kg body weight per day, in four divided doses. The daily dose should not exceed 250 mg (10ml gel) four times day.

In case of localized lesions of the mouth, a small amount of gel may be applied 2-4 times a day directly to the affected area with a clean finger.

For best results, **Symbiotrin** oral gel should be kept in contact with the affected area as long as possible. The treatment should be continued for at least a week after symptoms have disappeared.

For oral candidiasis, dental prosthesis should be removed at night and brushed with the gel.

CONTRAINDICATIONS

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

WARNING AND PRECAUTION

If the concomitant use of Miconazole and anticoagulant is considered, the anti-coagulant effect should be monitored and titrated. Miconazole and Phenytoin plasma level should also be monitored when used concomitantly. In infants and young children, caution must be taken to ensure that the gel does not obstruct the throat.

SIDE EFFECTS

Occasionally nausea and vomiting, diarrhoea with long term use and rarely allergic reactions.

USE IN PREGNANCY AND LACTATION

There is no information regarding the safety of Miconazole oral gel during pregnancy. So Miconazole oral gel should be avoided in pregnant women if possible or 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.

USE IN CHILDREN AND ADOLESCENTS

Safety and efficacy have not been established under the age of 6 months.

DRUG INTERACTIONS

Miconazole can inhibit the metabolism of drugs metabolized by the cytochrome P450-3A and -2C9. Miconazole oral gel should not be used during treatment with Cisapride, Triazolam, Oral Midazolam, Mizolastine, Quinidine, Simvastatin and Lovastatin.

OVERDOSAGE

Consult a registered physician immediately in case of hypersensitivity reactions.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Each tube contains 15 gm oral gel.