

Orogurd[®] 2% w/w

Miconazole BP Oral Gel

DESCRIPTION

Orogurd[®] oral gel is a preparation of Miconazole, which is used to prevent and treat fungal and bacterial infections of the mouth and throat. **Orogurd[®]** oral gel works by destroying the fungus and associated bacteria which may be present. **Orogurd[®]** oral gel possesses an antifungal activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain gram-positive bacilli and cocci. Its activity is based on the inhibition of the ergosterol biosynthesis in fungi and the change in the composition of the lipid components in the membrane, resulting in fungal cell necrosis.

INDICATIONS

Orogurd[®] oral gel is indicated for the treatment and prevention of fungal infections of the oropharynx and of superinfections due to Gram-positive bacteria.

DOSAGE & ADMINISTRATION

For oral administration: Dosage is based on 15 mg/kg/day

Adults: 1-2 tea-spoonfuls (5 -10 mL) of gel four times daily, after food

Children aged 6 years and over: One tea-spoonful (5 mL) of gel four times daily

Children aged 2-6 years: One tea-spoonful (5 mL) of gel twice daily

Infants under 2 years: Half tea-spoonful (2.5 mL) of gel twice daily

Elderly patients: Same as adults dose

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 candidiasis, dental prostheses should be removed at night and brushed with the gel.

The lower age limit should be increased by 1-2 months for infants who are pre-term, or infants exhibiting slow neuromuscular development.

SIDE-EFFECTS

Occasionally, nausea and vomiting have been reported and with long term treatment, diarrhea. In rare instances, allergic reactions have been reported. There are isolated reports of hepatitis, for which the causal relationship with Miconazole oral gel has not been established.

CONTRAINDICATIONS

It is contraindicated

- In those patients with a history of hypersensitivity to Miconazole.
- In infants less than 4 months of age or in those whose swallowing reflex is not yet sufficiently developed.
- In patients with liver dysfunction.

PRECAUTIONS

If the concomitant use of the Miconazole and oral anticoagulants such as warfarin 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. Hence, the gel should not be applied to the back of the throat and each dose should be divided into smaller portions. Observe the patient for possible choking.

OVERDOSE

In the event of accidental overdose, vomiting and diarrhoea may occur.

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 man 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.

PHARMACEUTICAL PRECAUTION

Store in dry place and away from light. Keep out of reach of children.

PACKAGING

Orogurd[®] oral gel : Box containing a spoon (5 mL) and a tube of 15 g oral gel. Each gram oral gel contains Miconazole BP 20 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

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