



Miconazole 2% w/w

Sugar Free

Presentation

Dakrin oral gel : Each gm gel contains Miconazole BP 20 mg.

Pharmacodynamics

Miconazole 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 a demethylation step in the ergosterol biosynthesis. Ergosterol, the end-product of the biosynthetic pathway and the main sterol in yeast and fungi. The disruption in production of ergosterol disrupts the fungal cell membrane, causing holes to appear in it. These holes allow the essential constituents of the fungal cells to leak out and ultimately the fungal cells die.

Pharmacokinetics

The oral bioavailability of Miconazole is low (25-30%) because there is little absorption of Miconazole from the intestinal tract. Miconazole is systemically absorbed after administration as the oral gel.

Absorbed Miconazole is bound to plasma proteins (88.2%), primarily to serum albumin and red blood cells (10.6%).

The absorbed portion of Miconazole oral gel is largely metabolized; less than 1% of the administered dose is excreted unchanged in the urine. The terminal plasma half-life is 20-25 hours in most patients. The elimination half-life of Miconazole is similar in any renal impaired patient.

Indications

Dakrin oral gel is indicated-

- ❖ For the treatment of oral and gastrointestinal candidiasis.
- ❖ For eradication of fungal colonization in the mouth and gastrointestinal tract
- ❖ For the treatment of super infections due to gram-positive bacteria

Dosage and Administration

Dakrin oral gel is administered orally and should be taken after meals. For best results, the gel should be retained in the mouth as long as possible. Treatment continued for 48 hours after lesions have resolved.

- Children : Less than 2 yrs: 2.5 ml (½ supplied spoonfuls of gel) two times daily.
 2-6 yrs: 5 ml (1 supplied spoonfuls of gel) two times daily.
 Older than 6 yrs : 5 ml (1 supplied spoonfuls of gel) four times daily.
- Adults : 5-10 ml (1-2 supplied spoonfuls of gel) four times daily.

Missed Dose

Apply the missed dose as soon as you remember. In case of next dosing time, omit the missed dose and continue your usual course.

Contraindications

It is contraindicated in patients with a known hypersensitivity to Miconazole or to any other ingredients of the gel.

Precautions

It is advisable to monitor the effects of anticoagulants such as Warfarin/antiepileptic such as Phenytoin/oral hypoglycemic such as Sulfonyl ureas and Miconazole, if they are used concomitantly.

In Pregnancy and Lactation

There is no information concerning the safety of Miconazole oral gel during pregnancy and in lactating mother. So, cautions should be exercised.

Side Effects

It is usually well-tolerated.

Drug Interactions

Concomitant treatment with Terfenadine, Astemizole and Cisapride should be avoided because in vitro studies suggest that Miconazole may inhibit their metabolism, so these products might precipitated.

Miconazole may delay Phenytoin and Cyclosporine metabolism and this might precipitate Phenytoin and Cyclosporine toxicity, respectively.

Overdosage

Accidental overdosage may cause vomiting and diarrhoea. Treatment is symptomatic and supportive. A specific antidote is not available.

Storage Conditions

Store in a cool and dry place, away from light and out of children's reach.

Commercial Pack

Each pack has an aluminium collapsible tube containing 15 gm **Dakrin oral gel** with a spoon.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Gazipur, Bangladesh

