APPROVED NAME: MICONAZOLE ORAL GEL

TRADE NAME: MICOVAR ORAL GEL

REGISTRATION NO: TBA

PHARMACOLOGICAL CLASSIFICATION: A01AB09 Antiinfectives and antiseptics for local oral treatment

CATEGORY FOR DISTRIBUTION: POM

DESCRIPTION:
MICOVAR (MICONAZOLE) Oral Gel is transluscent gel containing miconazole, a broad spectrum antifungal agent. The oral gel contains 20 mg miconazole per gram.
It is preserved with 0.2 % m/m methyl paraben and 0.02 % m/m propyl paraben.

PHARMACOLOGICAL ACTION
Miconazole possesses antifungal activity against common dermatophytes, yeasts, ascomycetes, phycomycetes and adelomycetes as well as an antibacterial activity against certain gram-positive bacilli and cocci.

It acts by inhibiting biosynthesis of ergosterol in fungi membrane, resulting in fungal cell necrosis.

Oral bioavailability is low (25 – 30 %) because there is little absorption of miconazole from the intestinal tract. About 50 % of an oral dose may be excreted mainly unchanged in the faeces. It is extensively metabolized in the liver and less than 1 % of the administered dose is found unchanged in the urine. There are no active metabolites and terminal half-life is about 20 hours.

INDICATIONS
Micovar (miconazole) oral gel is indicated for the treatment of candidiasis of the oropharyngeal cavity and the gastro-intestinal tract.

CONTRAINDICATIONS
Known hypersensitivity to miconazole.
Liver dysfunction.

INTERACTIONS
MICOVAR ORAL GEL can inhibit the metabolism of medicines metabolised by the CYP3A4 and CYP2C9 enzyme systems. This can result in prolongation or increase of the effect of these medicines, including an increase in side effects.
Concomitant use of **MICOVAR ORAL GEL** is contraindicated with the following (see "**Contraindications**"):

- Substrates that prolong QT-interval including astemizole, dofetilide, halofantrine, mizolastine, pimozide, quinidine, sertindole and terfenadine.
- Ergot alkaloids.
- HMG-CoA reductase inhibitors such as simvastatin and lovastatin.
- Triazolam and midazolam.

Caution is advised with concomitant use of **MICOVAR ORAL GEL** and the following medicines:

- Oral anti-coagulants (e.g. warfarin).
- Oral hypoglycaemics (e.g. sulfonylureas).
- Phenytoin.
- HIV protease inhibitors (e.g. saquinavir).
- Certain antineoplastic medicines (e.g. the *Vinca* alkaloids, busulfan and docetaxel).
- Certain calcium channel blockers (e.g. dihydropyridines and verapamil).
- Certain immunosuppressants (e.g. ciclosporin, tacrolimus, sirolimus).
- Other medicines including alfentanil, alprazolam, brotizolam, buspirone, carbamazepine, cilostazol, disopyramide, ebastine, methylprednisolone, midazolam IV, reboxetine, rifabutin, sildenafil and trimetrexate.

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PREGNANCY AND LACTATION
Potential hazards of this drug during pregnancy should always be weighed against the expected therapeutic benefits. There is no data available on the excretion of Miconazole in human milk, therefore caution should be excercised when recommending Micovar Oral Gel to nursing women.

SIDE EFFECTS
May cause gastrointestinal discomfort such as nausea,vomiting and diarrhea.
This medicinal product contains methylparaben and propylparaben which may cause allergic reactions.
Allergic reactions and isolated cases of hepatitis have been reported.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Micovar should not affect alertness or driving ability.

OVERDOSAGE
Symptoms
Miconazole is not highly toxic. Overdosage may lead to vomiting and diarrhea.

Treatment
There is no specific antidote for miconazole.
Treatment of overdosage is symptomatic and supportive.

DOSAGE AND ADMINISTRATION
Infants: up to 1 year ¼ measuring spoon of gel four times daily.
Children: 1 – 12 years ½ measuring spoon of gel four times daily.
Adults: 1 measuring spoon of gel four times daily.

The Gel should be kept in the mouth for as long as possible.
Treatment should be continued for at least a week after the symptoms have disappeared.
For oral candidiasis, dentures must be removed at night and brushed with the gel.

PRESENTATION
Micovar 2 % m/m oral gel is supplied in tubes of 30g or 40 g with a 5 ml measuring spoon.

STORAGE
Do not store above 30 °C.
Keep out of reach of children.

MANUFACTURER (MARKETING AUTHORISATION HOLDER)
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