Micogel Oral Gel 20mg
(Miconazole)

مائیکوجیل اورل جیل ۲۰ ملی گرام
(مائیکونازول)

COMPOSITION:
Each gram contains:
Miconazole.....20mg
(BP specifications)

DESCRIPTION:
Miconazole is an azole antifungal with broad-spectrum activity used to treat fungal infections affecting the vagina, mouth and skin, including candidiasis.

MECHANISM OF ACTION:
Miconazole nitrate is active against dermatophytes and pathogenic yeasts and many Gram-positive bacteria. The clinical efficacy of miconazole has been demonstrated against dermatophytes, Candida spp., Aspergillus spp., dimorphous fungi, Cryptococcus neoformans, Malassezia spp. and Torulopsisglabrata. Miconazole also has an antibacterial activity against some 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:
Oral treatment of candidosis of the oropharynx.
Miconazole gel is for use in adults, children and infants 4 months and older. Consideration should be given to official guidance on the appropriate use of antifungal agents.

DOSAGE & ADMINISTRATION:
For oral administration.
1 measuring spoon (provided) is equivalent to 124 mg miconazole per 5 mL gel.
Oropharyngeal candidosis
Infants: 4-24 months: 1.25 mL (1/4 measuring spoon) of gel, applied four times a day after meals. Each dose should be divided into smaller portions and the gel should be applied to the affected area(s) with a clean finger. The gel should not be applied to the back of the throat due to possible choking. The gel should not be swallowed immediately, but kept in the mouth as long as possible.
Adults and children 2 years of age and older: 2.5 mL (1/2 measuring spoon) of gel, applied four times a day after meals.
The gel should not be swallowed immediately, but kept in the mouth as long as possible.
The treatment should be continued for at least a week after the symptoms have disappeared.
For oral candidosis, dental prostheses should be removed at night and brushed with the gel.

PHARMACOKINETICS:
Absorption:
Miconazole is systemically absorbed after administration as the oral gel. Administration of a 60 mg dose of miconazole as the oral gel results in peak plasma concentrations of 31 to 49 ng/mL, occurring approximately two hours post-dose.
Distribution:
Absorbed miconazole is bound to plasma proteins (88.2%), primarily to serum albumin and red blood cells (10.6%).
Metabolism and Elimination:
The absorbed portion of miconazole is largely metabolized; less than 1% of an administered dose is excreted unchanged in the urine. The terminal half-life of plasma miconazole is 20 to 25 hours in most patients. The elimination half-life of miconazole is similar in renally impaired patients. Plasma concentrations of miconazole are moderately reduced (approximately 50%) during hemodialysis. About 50% of an oral dose may be excreted in the faeces partly metabolized and partly unchanged.

PRECAUTIONS:
Miconazole is systemically absorbed and is known to inhibit CYP2C9 and CYP3A4 which can lead to prolonged effects of warfarin. Bleeding events, some with fatal outcomes, have been reported with concurrent use of miconazole oral gel and warfarin. If the concomitant use of Micogel Oral Gel with an oral anticoagulant such as warfarin is planned, caution should be excercised and the anticoagulant effect must be carefully monitored and titrated. Patients should be advised that if they experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit, to stop treatment with miconazole and seek medical advice. Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Micogel and with other miconazole formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. It is advisable to monitor miconazole and phenytoin levels, if these two drugs are used concomitantly. In patients using certain oral hypoglycemic such as sulphonylureas, an enhanced therapeutic effect leading to hypoglycaemia may occur during concomitant treatment with miconazole and appropriate measures should be considered.
Choking in infants and young children
Particularly in infants and young children (aged 4 months – 2 years), 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. Each dose should be divided into smaller portions and applied into the mouth with a clean finger. Observe the patient for possible choking. Also due to the risk of choking, the gel must not be applied to the nipple of a breast-feeding woman for administration to an infant. It is important to take into consideration the variability of the maturation of the swallowing function in infants, especially when giving miconazole gel to infants between the ages of 4-6 months. The lower age limit should be increased to 5-6 months of age for infants who are pre-term, or infants exhibiting slow neuromuscular development. Serious skin reactions (e.g. Toxic epidermal necrolysis and Stevens-Johnson syndrome) have been reported in patients receiving Micogel Oral Gel. It is recommended that patients be informed about the signs of serious skin reactions, and that use of Micogel Oral Gel be discontinued at the first appearance of skin rash.
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, Micogel 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 Micogel Oral Gel to nursing mothers.

DRUG INTERACTIONS:
When using any concomitant medication the corresponding label should be consulted for information on the route of metabolism. Miconazole can inhibit the metabolism of drugs metabolised by the CYP3A4 and CYP2C9 enzyme systems. This can result in an increase and/or prolongation of their effects, including adverse effects. Oral miconazole is contraindicated with the coadministration of the following drugs that are subject to metabolism by CYP3A4:
- Substrates known to prolong the QT-interval e.g., astemizole, cisapride, dofetilide, mizolastine, pimozide, quinidine, sertindole and terfenadine
- Ergot alkaloids
- HMG-CoA reductase inhibitors such as simvastatin and lovastatin
- Triazolam and oral midazolam

When coadministered with oral miconazole the following drugs should be used with caution because of a possible increase or prolongation of the therapeutic outcome and/or adverse events. If necessary, their dosage should be reduced and, where appropriate, plasma levels monitored:
Drugs subject to metabolism by CYP2C9:
- Oral anticoagulants such as warfarin
- Oral hypoglycaemics such as sulphonylureas
- Phenytoin

Other drugs subject to metabolism by CYP3A4:
- HIV Protease Inhibitors such as saquinavir;
- Certain antineoplastic agents such as vinca alkaloids, busulfan and docetaxel;
- Certain calcium channel blockers such as dihydropyridines and verapamil;
- Certain immunosuppressive agents: cyclosporin, tacrolimus, sirolimus (= rapamycin)
- Others: carbamazepine, cilostazol, disopyramide, buspirone, alfentanil, sildenafil, alprazolam, brotizolam, midazolam IV, rifabutin, methylprednisolone, trimetrexate, ebastine and reboxetine.

SIDE EFFECTS:
Immune System Disorders:
Anaphylactic reaction, Hypersensitivity.
Nervous System Disorders:
Dysgeusia.
Respiratory, Thoracic and Mediastinal Disorders:
Choking.
Gastrointestinal Disorders:
Dry mouth, Nausea, Oral discomfort, Vomiting, Regurgitation, Diarrhoea, Stomatitis, Tongue discoloration.
Hepatobiliary Disorders:
Hepatitis.
Skin and Subcutaneous Tissue Disorders:
Angioedema, Toxic epidermal necrolysis, Stevens-Johnson syndrome, Urticaria, Rash, and Acutegeneralized exanthematous pustulosis, Drug reaction with eosinophilia and systemic symptoms
General Disorders and Administration Site Conditions:
Product taste abnormal.

CONTRAINDICATIONS:
Known hypersensitivity to miconazole, other imidazole derivatives or to any of the excipients. In infants less than 4 months of age or in those whose swallowing reflex is not yet sufficiently developed.
In patients with liver dysfunction.
Coadministration of the following drugs that are subject to metabolism by CYP3A4:
- Substrates known to prolong the QT-interval e.g., astemizole, cisapride, dofetilide, mizolastine, pimozide, quinidine, sertindole and terfenadine
- Ergot alkaloids
- HMG-CoA reductase inhibitors such as simvastatin and lovastatin
- Triazolam and oral midazolam

STORAGE & INSTRUCTIONS:
Store between 15-25°C. Protect from heat, sunlight and moisture. Do not freeze or refrigerate. Keep away from the reach of the children.
To be sold on the prescription of a registered medical practitioner only. For oral use only.

HOW SUPPLIED:
MICOGEL Oral Gel: 20g Tube

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ ریفریجریٹر میں نہ رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ صرف اورل استعمال کے لیے۔

Manufactured by:
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