MICOZOL ORAL GEL

Miconazole nitrate (2% w/w)

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What Micozol is used for

It is used for the treatment and prevention of fungal infections of the mouth, throat, stomach or intestines.

How Micozol works

Micozol destroys both the fungus that causes the infection and some of the associated bacteria which may also be present.

Before you use Micozol

- When you must not use it
- allergic to miconazole or other ingredients of Micozol
- liver problems
- Before you start to use it
- Be careful when applying gel on infants or young children, so as not to cause choking. Doses should be divided to smaller amounts.
- Safety for use in pregnancy and during breastfeeding has not been established.
- Tell your doctor if you are on warfarin therapy.

- Taking other medicines

Medicines used below must be monitored:

- oral anticoagulants (prevent blood clot)
- saquinavir, tacrolimus, cyclosporin and sirolimus (for HIV)
- anticancers (busulfan, vinca alkaloids and docetaxel, trimetrexate,)
- verapamil and dihydropyridines (for hypertension)
- oral hypoglycemic (for diabetes)
- phenytoin, carbamazepine (for seizures)
- buspirone, alprazolam, brotizolam, reboxetine (mood disorders)
- alfentanil (for intense pain)
- sildenafil (for impotence)
- rifabutin (antibiotic)
- methylprednisolone (steroid)
- ebastine (antihistamine)

Medicines below should not be used:

- simvastatin and lovastatin (for cholesterol)
- terfenadine, astemizole, mizolastine (antihistamine)

- cisapride (for gastric motility)
- triazolam, midazolam (for anxiety)
- dofetilide (for irregular heartbeat)
- quinidine (for malaria)
- pimozide (for brain disorder)

How to use Micozol

- How much to use

Apply over affected area 4 times daily. Gel should be kept in the mouth longest possible and treatment should be continued for at least a week after symptoms disappear. Oral candidosis – dental protheses should be removed and brushed with gel at night.

When to use it

Please follow the advice of the doctor or pharmacist.

- How long to use it

You should check with your doctor or pharmacist.

- <u>If you forget to use it</u>

If you forget to use this medicine, use it as soon as you remember. Then continue using it at your usual time.

If you use too much (overdose)

If you have used too much Micozol, contact your doctor, an emergency department or a poison center immediately. Vomiting and diarrhoea may occur.

While you are using Micozol

- Things you must do

Inform your doctor of all the medications you are taking.

- Things you must not do

Do not stop using medication although you feel better after a few days, until the prescribed course is finished.

Things to be careful of

If you are pregnant, become pregnant, or are breastfeeding, you should not use Micozol unless advised by your doctor.

Side effects

Local irritations and sensitivity reactions due to allergy may occur. Mild gastrointestinal disturbances may occur if taken by mouth

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my

(Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Micozol

- Storage

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

- <u>Disposal</u>

Ask your pharmacist how to dispose of medicines no longer required.

Product description

- What it looks like White flavoured gel.

- Ingredients:

- Active ingredient: miconazole nitrate
- Inactive ingredients: popylene glycol, polyethylene glycol, cremophor RH-40, methyl parabens, propyl parabens, polyvinylpyrrolidone, maltodextrin, sodium saccharin, silbione 70460, buttermilk flavour, sodium citrate, sodium chloride, sugar and purified water.

- MAL number:

MAL06011687AZ

Manufacturer and Product Registration Holder

Prime Pharmaceutical Sdn. Bhd. 1505, Lorong Perusahaan Utama 1 Taman Perindustrian Bukit Tengah 14000 Bukit Mertajam, Penang, Malaysia.

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