

Miconazole Nitrate

DESCRIPTION:

Mycoheal[®] preparations for vaginal use contain miconazole nitrate, a synthetic antifungal agent.

PHARMACOLOGY:

Pharmacodynamic properties:

Miconazole combines a potent antifungal activity against common dermatophytes and yeasts with an antibacterial activity against certain gram-positive bacilli and cocci. Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis. In general, miconazole exerts a very rapid effect on pruritus, a symptom that frequently accompanies dermatophyte and yeast infections.

Pharmacokinetic properties:

Systemic absorption after intravaginal administration is limited. Eight hours after application, 90% of miconazole nitrate is still present in the vagina. Unchanged miconazole could not be traced in blood plasma or urine.

INDICATIONS:

Mycoheal[®] vaginal preparations are indicated in the local treatment of vulvovaginal candidosis and superinfection due to gram-positive bacteria.

Mycoheal[®] VAGINAL CREAM may also be used for the treatment of mycotic balanitis.

CONTRAINDICATIONS:

Mycoheal[®] is contraindicated in patients with known hypersensitivity to miconazole or to any of its ingredients.

SIDE EFFECTS:

Side effects are rare and mild in most cases. Most frequently reported were local irritation, pruritus and burning sensation, especially at the start of the treatment. Complaints of pelvic cramping, hives, skin rash have also been reported.

WARNINGS AND PRECAUTIONS:

- Should local sensitisation or an allergic reaction occur, the treatment should be discontinued.
- General hygienic measures should be observed to control sources of infection and reinfection.
- Appropriate therapy is indicated when the sexual partner is also infected.
- **Mycoheal[®]** vaginal preparations do not stain skin or clothes.
- Pregnancy and lactation: Although intravaginal absorption is limited, **Mycoheal[®]** should only be used in the first trimester of pregnancy if, in the judgement of the physician, the potential benefits outweigh the possible risks. It is not known whether miconazole nitrate is excreted in human milk. Caution should be exercised when using **Mycoheal[®]** vaginal preparations during lactation.
- Effects on ability to drive and use of machines: Not applicable.

DRUG INTERACTIONS:

- Miconazole administered systemically is known to inhibit

CYP3A4/2C9. Due to the limited systemic availability after vaginal application, clinically relevant interactions are unlikely to occur. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

- Contact should be avoided between certain latex products such as contraceptive diaphragms or condoms and **Mycoheal[®]** since the rubber may be damaged.

DOSAGE AND ADMINISTRATION:

- **Mycoheal[®] VAGINAL CREAM:** once daily before retiring, the contents of the applicator (about 5 g of cream) should be squeezed deeply into the vagina. Repeat this procedure for 7 days, even after pruritus and leukorrhoea have disappeared. The applicator should be washed after each use.
- **Mycoheal[®] 200 VAGINAL SUPPOSITORIES:** one suppository is inserted intravaginally once daily at bedtime for seven consecutive days.
- **Mycoheal[®] 400 VAGINAL SUPPOSITORIES OR OVULES:** one suppository or ovule is inserted intravaginally once daily at bedtime for three consecutive days.
- **Mycoheal[®] 1200 VAGINAL OVULES:** one ovule is inserted intravaginally at bedtime.

The entire treatment should be completed, even when the symptoms rapidly disappear. It should be continued during menstruation.

OVERDOSAGE:

In case of accidental ingestion, no problems are expected. However, if taken concomitantly, the effects and side effects of some other drugs can be increased: e.g. coumarin derivatives, oral hypoglycaemics and phenytoin.

In the event of accidental ingestion of large quantities of the drug, an appropriate method of gastric emptying may be used if considered appropriate.

PRESENTATIONS:

Mycoheal[®] VAGINAL CREAM: Tube of 50 grams. Each gram contains 20 mg Miconazole Nitrate

Mycoheal[®] 200 VAGINAL SUPPOSITORIES: Packs of 7 vaginal suppositories. Each vaginal suppository contains 200 mg Miconazole Nitrate.

Mycoheal[®] 400 VAGINAL SUPPOSITORIES: Packs of 3 vaginal suppositories. Each vaginal suppository contains 400 mg Miconazole Nitrate.

Mycoheal[®] 400 VAGINAL OVULES: Packs of 3 vaginal ovules. Each vaginal ovule contains 400 mg Miconazole Nitrate.

Mycoheal[®] 1200 VAGINAL OVULES: Packs of one vaginal ovule containing 1200 mg Miconazole Nitrate.

STORAGE CONDITIONS:

Vaginal Suppositories and Ovules: Store below 25°C. Do not freeze.

Vaginal Cream: Store below 25°C.

This is a medicament.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and its risks.
- Do not, by yourself, interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Manufactured by Dar Al Dawa, Na'ur - Jordan