

GYNO-FUNGITRIN

Vaginal Ovules

Composition

Each soft gelatine capsule contains Miconazole nitrate 400 mg.

Action

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.

Pharmacokinetics

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

Gyno-Fungitrin ovules are indicated for the local treatment of vulvovaginal candidiasis (moniliasis). In such cases, the diagnosis should be confirmed by KOH smear and/or cultures. Other pathogens commonly associated with vulvovaginitis should be ruled out by appropriate laboratory methods.

Contraindications

Known hypersensitivity to the drug.

Adverse Reactions

The incidence of vulvovaginal burning, itching or irritation was 2%, headaches (1.3%), other complaints (hives, skin rash) occurred with less than 0.5% incidence. The therapy-related dropout rate was 0.3%.

Precautions

General

Discontinue the drug if sensitization or irritation is reported during use.

Pregnancy

Since imidazoles are absorbed in small amounts from the human vagina, they should not be used in the first trimester of pregnancy unless the physician considers it essential to the welfare of the patient.

Dosage and Administration

One ovule inserted intravaginally once daily at bedtime for three consecutive days. Before prescribing another course of therapy, the diagnosis should be reconfirmed by smears and/or cultures to rule out other pathogens.

Presentation

Box of 3 soft gelatine capsules.