

INSTRUCTION
for medical use

DERMAZOLE

Composition:

substances: ketoconazole;

1 suppository contains ketoconazole 400 mg;

excipients: solid fat, butylated hydroxytoluene (E 320).

Pharmaceutical Form. Vaginal suppository.

Basic physical and chemical properties: suppository from white to light yellow color, torpedo-shaped.

Pharmacotherapeutic group.

Antimicrobial and antiseptic agents for use in gynecology.

Code ATC G01A F11.

Pharmacological properties.

Pharmacodynamics.

Ketoconazole is a synthetic derivative of imidazolidioxolan. It has a pronounced fungicidal and fungistatic effect on dermatophytes (*Trichophyton spp.*, *Epidermophyton floccosum*, *Microsporum spp.*), yeast fungus (*Candida spp.*, *Pityrosporum spp.*, *Torulopsis spp.*, *Cryptococcus spp.*, *Rhodotorula spp.*), dimorphous and higher fungus (zoomitsites) . Less sensitive to ketoconazole *Aspergillus spp.*, *Sporothrix schenkii*, some *Dermatiaceae*, *Mucor spp.* And other ficomyces, with the exception of *Entomophthales*. Ketoconazole is also active against gram-positive cocci (*Staphylococcus spp.*, *Streptococcus spp.*).

The mechanism of action is aimed at suppressing the biosynthesis of ergosterol and altering the lipid composition of the membrane of fungus, which leads to their circulation. The drug is also active against pathogens resistant to antifungal antibiotics (nystatin, levorin), as well as to clotrimazole. The development of secondary resistance during treatment with ketoconazole has not been observed until now.

Pharmacokinetics.

In the case of intravaginal use, the drug is poorly absorbed, only a small amount (less than 1%) gets into the systemic circulation. The maximum plasma concentration after application of 400 mg ketoconazole ranges from 0 to 10.7 ng / ml, which is considered as a trace and does not effect the systemic action.

Clinical characteristics.

Indication.

Treatment of acute and chronic recurrent vulvovaginal candidiasis. Prevention of fungal infections of the vagina with reduced resistance of the body and against the background of treatment with drugs that violate the normal microflora of the vagina.

Contraindication.

Individual hypersensitivity to any component of the drug.

Interaction with other drugs and other types of interactions.

When ketoconazole is co-administered with rifampicin and isoniazid, the concentration of ketoconazole in blood plasma is reduced. When co-administered with cyclosporin, indirect anticoagulants and methylprednisolone, ketoconazole may increase the plasma concentration of the latter. The practical significance of these interactions in the treatment of ketoconazole in the form of vaginal suppositories is unknown.

Peculiarities of use.

In rare cases, local allergic reactions may occur in the sexual partner. To reduce the risk of recurrence of the disease, it is recommended that the sexual partner be treated simultaneously. Avoid contact with latex drugs (contraceptive diaphragms, condoms) due to the reduced reliability of mechanical contraception, so the possibility of pregnancy or infection with sexually transmitted diseases is not excluded. During treatment it is necessary to refrain from sexual intercourse. The drug is recommended for use at night, because the drug has an osmotic and drainage effect, which is accompanied by an increase in vaginal discharge. It is recommended for the period of treatment with Dermazol at night to use sanitary napkins.

In the development of adverse reactions, including hypersensitivity reactions, the drug should be discontinued and seek medical advice.

The product contains butylhydroxyanisole (E 320), which may cause local skin reactions (e.g. contact dermatitis) or irritation of the mucous membranes.

Use during pregnancy or breastfeeding.

Although systemic absorption in the intravaginal use of ketoconazole is extremely low or absent, adequate controlled clinical trials with regard to the safety of ketoconazole do not exist in pregnant women. The drug should not be used in the first trimester of pregnancy.

In the II-III trimester of pregnancy and during lactation, the product should only be used if the expected benefit to a woman exceeds the potential risk for the fetus or child.

Effect on reaction rate when driving motor transport or operating other mechanisms.

It usually does not affect, but you should take into account the possibility of dizziness in people with hypersensitivity.

Dosage and administration.

The suppository is released from the strip and inserted deep into the vagina in the position lying on the back with knees bent and tucked up to the chest with legs or on hunkers. Suppository should not be cut into pieces, because such a change in the storage conditions of the drug may lead to a disturbance in the distribution of the active substance. Use 1 suppository per day before bedtime for 3-5 days. If necessary, the course of treatment should be repeated until clinical and confirmed by laboratory tests of recovery. For chronic candidiasis use 1 suppository for 10 days. It is recommended to wash your hands after the use of the drug to prevent accidental exposure of its residues to the eyes, to the mucous membranes or to the skin.

Children.

There is no experience with the use of the drug in children, therefore, it should not be prescribed to this age group of patients.

Overdose

In case of overdose, local reactions are possible such as: flushing, burning, itching, irritation of the vaginal mucosa. In such cases, dipping with water is recommended.

Adverse reactions.

Adverse reactions usually occur rarely and quickly disappear after discontinuation of the drug.

Local reactions: irritation of the vaginal mucosa, accompanied by itching, burning sensation, hyperemia.

Skin and subcutaneous tissue: itching, rash, hyperemia.

Immune system: hypersensitivity reactions, including anaphylactic and anaphylactoid reactions, angioneurotic edema, urticaria.

Digestive tract: nausea, abdominal pain.

Nervous system: dizziness.

Shelf-life.

2 years.

Storage conditions.

Store at the temperature not more than 25 °C in the original package.

Keep out of reach of children.

Package.

5 suppositories are in a strip. 1 or 2 strips are in a cardboard packaging.

Conditions of supply.

Without prescription.

Manufacturer.

KUSUM HEALTHCARE PVT LTD.

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Date of last revision.