MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

Stamp: Ministry of Health of Russia ЛП-004092-230117. Approved.

INSTRUCTION LEAFLET
FOR MEDICAL USE OF THE MEDICINAL PRODUCT
Clotrimazol

Product licence number:

Brand name: Clotrimazol

Generic name: Clotrimazol

Pharmaceutical form: vaginal cream

Product formulation:

100 g of the cream contain:

Active ingredients: Clotrimazol – 2,0 g;

Excipients: sorbitan stearate – 2,0 g, cetyl palmitate – 3,00 g cetostearyl alcohol [cetyl alcohol 60% and stearyl alcohol 40%] – 10,0 g, polysorbate-60 – 1,5 g, octyldodecanol – 13,5 g, benzyl alcohol – 1,0 g, purified water – 67,0 g.

Description: homogeneous cream of white color, smell-less.

Pharmacotherapeutic group: antimycotic agent.

ATC code: G01AF02

Pharmacological properties

Pharmacodynamic properties

Clotrimazol is a broad-spectrum antifungal agent for local use. The antimycotic effect of the active ingredient Clotrimazol (derivative of imidazole) is associated with an alteration of the synthesis of Ergosterol, which is part of the cell membrane of fungi, which changes the membrane permeability and causes subsequent cell lysis. In small concentrations, it acts fungistatically, and in large concentrations, it is fungicidal, and not only on proliferating cells. In fungicidal concentrations, it interacts with mitochondrial and peroxidase enzymes, resulting in an increase in the concentration of hydrogen peroxide to a toxic level, which also contributes to the destruction of fungal cells.

It is effective against dermatophytes, yeasts, molds and protozoa. It has an antimicrobial effect against gram-positive (Streptococcus spp., Staphylococcus spp.) and anaerobes (Bacteroides spp., Garnerella vaginalis). Clotrimazol has no effect on lactobacilli. In vitro, at a concentration of 0,5 - 10 μg/ml, Clotrimazol inhibits the multiplication of bacteria of the Corinebacteria family and gram-positive cocci (with the exception of enterococci); has a Trichomonacid effect at a concentration of 100 μg/ml.

Pharmakokinetics

When using Clotrimazol intravaginally, its absorption is equal to 3-10% of the administered dose. High concentrations in vaginal secretions and low concentrations in blood persist for 48 to 72 hours. In the liver, it is metabolized to inactive metabolites, excreted by the kidneys and through the intestinal tract.

Indications

- genital infections caused by yeast-like fungi of the genus Candida (vulvovaginal candidiasis);

If necessary, please, consult your physician before using the drug.

Contra-indications

- hypersensitivity to Clotrimazol or other the components of the drug, especially to cetostearyl alcohol;
- period of menstruation;
- I trimester of pregnancy;

Carefully

Breast-feeding period

Administration during pregnancy and breast-feeding period

The use is contraindicated during I trimester of pregnancy. The question of the advisability of using the drug in the II-III trimesters of pregnancy should be decided individually after consulting a physician.

The use of the drug during breast-feeding period is allowed only if, in the opinion of the physician, the potential benefit of using the cream for the mother outweighs the possible risk for the child.

Posology and method of administration

Locally. For intravaginal use only.

For 6 consecutive days, once a day in the evening before sleeping, inject the contents of the filled applicator (about 5 g) as deep as possible into the vagina, in the supine position, with slightly bent legs.

Application of vaginal cream using a disposable applicator:

1. Open the tube and screw on the disposable applicator.
2. Gently squeeze the tube and fill the disposable applicator until the plunger is fully extruded.
3. Unscrew the applicator from the tube. Insert the applicator as deep as possible into the vagina (preferably in the supine position) and squeeze out the contents of the applicator by pressing the plunger.
4. Remove the disposable applicator after use and dispose.

Use the drug only according to the method of administration and in the doses indicated in the

instructions for use.

A repeated course of treatment is possible after consulting your attending physician.

If after treatment there is no improvement or new symptoms appear, you should consult your physician.

Adverse drug reaction

According to the World Health Organization (WHO), unwanted effects are classified according to their frequency of development as follows: very often (≥ 1/10), often (≥ 1/100, <1/10), infrequently (≥ 1/1000, < 1/100), rarely (≥ 1/10000, <1/1000) and very rarely (< 1/10000); the frequency is unknown (the frequency of occurrence of the events cannot be determined from the available data).

Abnormalities of immune system:

the frequency is unknown: allergic reactions with such symptoms as urticaria, fainting, arterial hypotension, shortness of breath.

Abnormalities of the gastrointestinal tract:

the frequency is unknown: abdominal pains.

Abnormalities of the skin and subdermal tissue:

the frequency is unknown: in case of hypersensitivity to the active substance or another component of the drug, such as cetostearyl alcohol, allergic reactions may occur.

Abnormalities of the kidneys and the urinary tract:

the frequency is unknown: frequent urination, intercurrent cystitis.

Abnormalities of the genital organs:

the frequency is unknown: itching, burning, hyperemia and edema of the vaginal mucous membrane, ulceration of the vaginal mucous membrane, rash, pain in the pelvic region.

Others:

the frequency is unknown: headache, gastralgia.

If any of the adverse reactions indicated in the instructions are aggravated or you notice any other adverse reactions not listed in the instructions, notify your physician.

Overdosage

In case of an overdose, the following symptoms are possible: dizziness, nausea, vomiting.

Treatment: There is no specific antidote. In case of accidental ingestion, symptomatic treatment should be carried out.

Interaction with other medicinal products

When vaginal administering, Clotrimazol reduces the activity of amphotericin B and other polyene antibiotics.

In case of the simultaneous use with Natamycin or Nystatin, the activity of Clotrimazol may be

reduced.

The simultaneous use of Clotrimazol vaginally and Tacrolimus and Sirolimus orally may lead to an increase in the concentration of the latter in the blood plasma, therefore, patients should be monitored for the occurrence of symptoms of their overdose, if necessary, with the measurement of plasma concentrations.

Precaution

Read the instructions for use carefully before using the drug. Please keep the instructions, you may need them again. If you have any questions, consult your physician.

The drug with which you are being treated is intended for you personally and should not be passed on to any other people, since it can harm them even if they have the same symptoms as you.

If allergic reactions or irritation occurs at the injection site, treatment should be discontinued.

The drug should not be used during menstruation; it is advisable to start treatment after menstruation.

In the event of simultaneous infection of the labia and adjacent areas (vulvitis candidiasis), additional topical treatment with Clotrimazol should be performed.

During pregnancy, vaginal cream treatment should be performed without an applicator.

To prevent infection, simultaneous treatment of sexual partners is necessary.

During the period of treatment, it is recommended to refrain from sexual intercourse.

It is recommended to use contraceptives during treatment. The risk of rupture of a condom or diaphragm increases when they are used simultaneously with the use of the drug. You should use reliable methods of contraception.

Hygiene rules should be followed to prevent reinfection.

If clinical signs of infection persist after completion of treatment, a repeated microbiological study should be performed to confirm the diagnosis.

Effects on ability to drive and use machines

The drug does not affect the ability to drive and engage in other potentially hazardous activities that require increased concentration of attention and high speed of psychomotor reactions.

Pharmaceutical form and presentation

Vaginal cream, 2 %.

20 g aluminum tubes. Tube with disposable applicators (3 pieces) for intravaginal administration in an outer carton along with instructions for use.

Storage conditions

Store at a temperature not higher than 25ºC.

Keep out of reach of young children.

Expiry date

3 years.

Do not use after the expiry date.

Dispensing requirements

No prescription.

Marketing authorization holder:

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