INSTRUCTION
for medical use of medicinal product
LEKNAZOLE®

Composition:
active ingredient: 1 suppository contains 150 mg of econazole nitrate;
excipients: polyethylene oxide 400, polyethylene oxide 1500, hard fat, cetyl alcohol, titanium dioxide (E 171), silica colloidal anhydrous.

Pharmaceutical form. Vaginal suppositories.

Pharmacotherapeutic group. Antimicrobials and antiseptics used in gynaecology.
ATC Code G01A F05.

Clinical characteristics.
Indications.
Vulvovaginal mycoses caused by pathogens of fungal infections sensitive to econazole.

Contraindications.
Hypersensitivity to econazole nitrate or any of its components.

Dosage and administration.
Before using suppository:
− remove one suppository in the primary packaging from the blister pack by pulling along the line of perforations;
− then pull apart at the edge of the film releasing the suppository from the primary packaging.

Treatment course for adults is 3 days, one suppository into the posterior vaginal fornix once daily at bedtime, preferably in the supine position. In case of relapse or positive culture after one week, the treatment should be repeated.

Undesirable effects.
Skin and subcutaneous tissue disorders: skin and subcutaneous tissue disorders. There are known cases of generalized allergic reactions, including angioedema and urticaria.
General disorders and administration site conditions: general disorders and site conditions; very rarely − localized mucocutaneous reactions at the administration site, such as erythema, rash, contact dermatitis, skin peeling, burning sensation and itching, pain, irritation, swelling at the injection site.

Overdose.
Overdose was not reported.
Undesirable reactions can increase.
Accidentally swallowing the drug can cause nausea, vomiting and diarrhoea. In such cases, symptomatic therapy should be initiated.

Use during pregnancy and in nursing women.
The drug can be absorbed into the systemic circulation from the vagina, therefore it should not be used during Trimester I of pregnancy, unless the drug is considered essential to the welfare of the patient. During the second and third trimesters of pregnancy, the drug can be used if the potential benefit to the mother outweighs the potential risk to the fetus.
It is not known whether econazole nitrate is excreted in human milk. Therefore its use is not recommended in breast-feeding women or breast-feeding should be discontinued during treatment.

Pediatric patients.
Safety and efficacy of the drug has not been established in children. The use of this drug is therefore not recommended in this category of patients.

Special warnings.
Place suppositories in a cool place for 30 minutes before application. The suppositories include hard fat, which can destroy a rubber contraceptive diaphragm or a latex condom and reduce their effectiveness. Therefore, combination of these drugs should not be used.
Treatment should be discontinued at the signs of irritation or hypersensitivity. Patients with sensitivity to imidazoles have also reported sensitivity to econazole nitrate.
Leknazole® should not be used in conjunction with other internal or external treatment of the genitalia.
Patients using spermicidal contraceptives should consult their physician since any local vaginal treatment may inactivate the spermicidal contraceptive.

Effects on ability to drive and use machines.
No data.

Interactions with other medicinal products and other forms of interaction
The concurrent use of condoms or diaphragms with econazole should be avoided. This interaction cause reduced drug effectiveness and weakened barrier contraceptive strength.
Leknazole® should not be combined with other gynaecological drugs for intravaginal or topical use containing mineral oil, vegetable oil or petrolatum as a base.
Appropriate studies have not been conducted. Based on the chemical similarity of econazole with imidazole derivatives, there is a possibility of competitive interactions of econazole nitrate with substances that are metabolized by CYP3A/2C29 enzymes. However, clinically relevant interactions may occur taking into account the fact that the drug is weakly absorbed into the systemic circulation.
Caution should be exercised and blood clotting parameters should be monitored in patients who are taking oral anticoagulants, such as warfarin and acenocoumarol. Adjustment of the oral anticoagulant dosage may be necessary during the treatment with econazole and after its termination.

Pharmacological properties.
Pharmacodynamics.
The drug is a triazole fungicide. It provides anti-mycotic activity against dermatophytes, yeasts and moulds. The drug is effective against Gram-positive and Gram-negative bacteria. Econazole nitrate destroys the fungal cell membranes by increasing the fungal cell wall permeability and damaging the fungal cytoplasmic intracellular membranes. Acyl residues of unsaturated fatty acids of membrane phospholipids may be the exposure sites.
Topical application provides rapid results. Symptoms of vaginitis completely disappear within 24-48 hours after treatment begins.
Pharmacokinetics.
Econazole nitrate is poorly absorbed after vaginal application.
Less than 1% of the dose is excreted in the feces and urine.

Pharmaceutical particulars.
Basic physical and chemical properties: White, bullet-shaped suppositories.

Shelf-life. 3 years.

Storage. Store in original package at temperature not exceeding 25 °C. Keep away from children.

Nature and contents of container. 3 suppositories in a blister, 1 blisters in a box.

Prescription status. By prescription.

Manufacturer. Joint Stock Company «Lekhim-Kharkiv»

Location. Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36

Date of the last revision.