

INSTRUCTION
for medical use of medicinal product
LEKFUCIN®

Composition:

active ingredient: chlorquinaldol;

1 suppository contains 15 mg of chlorquinaldol;

excipients: preparation OC-20 (mixture of polyoxyethylene glycol ethers of higher fatty alcohols), cetostearyl alcohol, poloxamer 188, propylene glycol, polyethylene oxide 400.

Pharmaceutical form. Vaginal suppositories.

Main physicochemical properties: white or off-white suppositories of spherical shape.

Pharmacotherapeutic group. Antimicrobial and antiseptic drugs, which are used in gynaecology. ATC code G01A C03.

Pharmacological properties.

Pharmacodynamic properties.

Suppositories have antifungal effects on ascomycetes of the genus *Aspergillus* and the genus *Penicillium*, yeast and yeast-like (*Candida albicans*, etc.) fungi and dermatophytes. Lefkucin® suppositories have antibacterial action against gram-positive and gram-negative bacteria (*Streptococcus pyogenes*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Corinebacterium diphtheriae*, *Salmonella spp.*, *Escherichia coli*), and antiprotozoal effect (*Entamoeba histolitica*, *Trichomonas vaginalis*, *Lambliia intestinalis*).

The drug is characterized by moderate hyperosmolar activity due to which it absorbs vaginal discharge.

Pharmacokinetic properties.

Chlorquinaldol is not absorbed during vaginal application and does not have resorptive effect.

Clinical particulars.

Therapeutic indications.

Treatment of colpitis and vulvovaginitis of fungal and non-specific bacterial aetiology.

Contraindications.

Hypersensitivity to chlorquinaldol or to any of the product excipients.

Interaction with other medicinal products and other forms of interaction.

No available data on interaction.

Special warnings and precautions for use.

Since the drug has a wide range of antimicrobial action, it should be used for mixed bacterial and fungal infections, especially in the initial period of treatment (before identifying the causative agents). It is advisable to avoid vaginal douching during the period of suppository use.

In vulvovaginal candidiasis, the treatment should be carried out in combination with oral administration of nystatin tablets to eliminate foci of candidal infection in the gastrointestinal tract. Combination therapy is recommended in non-specific colpitis: vaginally – Lefkucin® suppositories, and orally – the relevant systemic antibiotics to inhibit infection in the urinary tract. At the same time, it is necessary to treat the sexual partner.

Chinofucin contains propylene glycol, which can cause irritation.

Pregnancy and lactation.

Given the possibility of developing general reactions, the drug use during pregnancy or breastfeeding is possible only if the expected benefit from the use for the mother is dominated over the possible risk to the foetus.

Effects on ability to drive and use machines.

Not available.

Posology and method of administration.

Before using the suppository, the following should be done:

- tear off one suppository in the primary packaging along the perforation line of the blister package;
- pull the edges of the film tearing it in different directions, and release the suppository from the primary packaging.

The drug is used for adult women vaginally, 1 suppository per day for 20 days or 1 suppository twice a day for 10 days. Before use, the suppository should be moistened with water. Therapy should be started at the beginning of the menstrual cycle.

Paediatric population.

Due to the lack of clinical data, it is not recommended to prescribe the drug to children.

Overdose.

No cases of overdose were observed.

Increased adverse reactions are possible. In such cases, symptomatic therapy should be carried out, if necessary.

Undesirable effects.

Allergic reactions, including rash, itching in the genital area, contact dermatitis are possible. Injection site reactions, injection site burning and irritation are possible.

Cetostearyl alcohol can cause local skin reactions and contact dermatitis.

Propylene glycol may cause irritation.

Shelf life. 3 years.

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

Package. 5 suppositories in a blister, 1 or 2 blisters in a pack.

Prescription status. By prescription.

Manufacturer. Joint Stock Company «Lekhim-Kharkiv»

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

Date of last revision.