

Lomexin®

vaginal cream, 200 mg ovules,
600 mg ovule, vaginal douche

fenticonazole nitrate Vaginal preparations

COMPOSITION

• vaginal cream 2%: 100 g contain:
Fenticonazole nitrate 2 g.

Excipients: Propylene glycol, hydrogenated lanolin, almond oil, polyglycolic ester of fatty acids, cetyl alcohol, glyceryl monostearate, sodium edetate, purified water.

• 200 mg ovules: each ovule contains:
Fenticonazole nitrate 200 mg.

Excipients: Triglycerides of saturated fatty acids, precipitated silica, gelatin, glycerin, titanium dioxide, sodium ethylhydroxybenzoate, sodium propylhydroxybenzoate.

• 600 mg ovule: each ovule contains:
Fenticonazole nitrate 600 mg.

Excipients: liquid paraffin, white soft paraffin, soya lecithin, gelatin, glycerin, titanium dioxide, sodium ethylhydroxybenzoate, sodium propylhydroxybenzoate.

• vaginal douche 0.2%: 100 ml of solution contain: Fenticonazole nitrate 200 mg.

Excipients: propylene glycol, benzalkonium chloride, alkylamidobetaine solution, purified water.

PRESENTATIONS

2% vaginal cream: tube of 78 g.

200 mg ovules: box of 3.

600 mg ovules: box of 1.

0.2% vaginal douche: 1 pack
contains 5 bottles of 150 ml.

PROPERTIES

Lomexin® exerts fungistatic and fungicidal action on dermatophytes (responsible for most mycotic skin infections), pathogenic yeasts, dimorphic fungi and moulds. In addition Lomexin® is active against gram positive bacteria and is therefore indicated in mycoses associated with bacterial superinfections. Lomexin® is also active, both in vitro and vivo, against *Trichomonas vaginalis*.

INDICATIONS

Genital candidiasis (vulvovaginitis, colpitis, infectious fluor).

CONTRAINDICATION

Ascertained hypersensitivity to the product.

WARNINGS

Although transcutaneous and vaginal absorption of Fenticonazole is very poor, use of the preparation is not recommended in pregnancy.

DOSAGE AND ADMINISTRATION

Vaginal ovules:

One 200 mg ovule at bedtime for three consecutive days, according to medical instructions.

One 600 mg ovule at bedtime followed by a second administration 3 days later if symptoms persist. The ovules must be introduced deep into the vagina and pushed well up to the fornix.

Vaginal cream:

One applicatorful (about 5 g) is administered deeply into the vagina.

The product is to be used in the evening, before going to bed, and if necessary in the morning as well.

To avoid re-infection it is recommended that the partner undergoes concurrent local (glans and prepuce) treatment with the cream.

Vaginal douche:

1-2 times a day for 7 days as adjuvant treatment in order to prevent relapses.

SIDE EFFECTS

Lomexin® (Fenticonazole) is generally well tolerated by the mucous membranes; only exceptionally mild and transient erythematous reactions have been reported. After topical application or intravaginal administration a slight burning sensation may occur, usually subsiding soon. Should more persistent irritation occur or resistant micro-organisms develop, suspend the treatment and seek the doctor's advice. Due to Lomexin® poor absorption, no systemic effects should occur, provided the above instructions are carefully observed.

Keep out of children's reach.

Do not use the product after expiry date.

Instructions for the use of vaginal cream applicator

1) Remove the tube's cap, screw in place the applicator and tighten it.

2) Squeeze the lower end of the tube to allow the cream into the applicator. If piston offers a certain resistance, pull it gently. The applicator must be totally filled with cream unless otherwise specified by the physician.

Unscrew the applicator and immediately replace the cap on the tube.

3) In the position as shown in the diagram, introduce gently the applicator deep into the vagina and push out all the cream. Withdraw gently the applicator and wash it thoroughly after use.

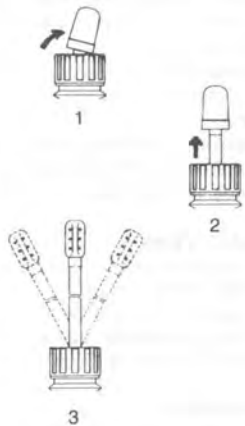


Instructions for the use of vaginal douche bottle

1) Holding the bottle upright, break the cap by pushing it sideways.

2) Use the cap to hold the tip of the dispenser and pull it out strongly.

3) The dispenser can be rotated as required. Discard the cap, and gently introduce the dispenser deep into the vagina (in the position as in diagram 3 above). Empty the content by squeezing the bottle. A slow irrigation favors better disinfection.



Vaginal Cream and Douche manufactured in
Zouk Mosbeh Lebanon by
ALGORITHM S.A.L.

Ovules Packed in
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