

## **PACKAGE LEAFLET: Information for the patient**

### **MELIOEKO**

Cream – 1%

(Econazole nitrate)

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

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### **1. WHAT MELIOEKO IS AND WHAT IT IS USED FOR**

Melioeko contains the active substance econazole nitrate, which is an imidazole derivative with antifungal activity. It is effective on: *Candida albicans*, *Candida glabrata*, *Candida tropicalis*, *Candida parapsilosis*, *Candida pseudo-tropicalis*, *Candida krusei*, *Candida stellatoidea*, *Trichophyton rubrum*, *Trichophyton mentagrophytes*. Econazole is selectively fixed on cytochrome P-450 and inhibits the membrane synthesis. Resistance occurs rarely.

Econazole nitrate absorption is low in topical or vaginal use.

After repeated applications of the cream or ovules, systemic absorption of the active substance in the vaginal mucosa is about 1%. This small percentage does not cause problems in distribution,

metabolism and elimination.

**The gynecological cream 1% is indicated in:**

- the treatment of genital mycoses caused from bacterias sensitive to econazole;
- mycotic vulvovaginitis, mycotic balanitis.

**2. BEFORE YOU USE MELIOEKO**

**Do not use Melioeko if you:**

- are hypersensitive to econazole nitrate or to any imidazole derivative antifungal agent and also to any of the excipients of the cream;
- are under 16 years old.

**Take special care with Melioeko**

You should consult your doctor or pharmacist before using this drug if you are using a contraceptive method like “diaphragm”, because the vaginal cream may damage the rubber and stop the action of this contraception. You should talk to your doctor about another method of contraception while using this drug.

The cream may cause irritation and burning sensation. If irritation occurs, the treatment should be interrupted due to any possible hypersensitivity reaction. The gynecological cream should be applied even in areas around the vagina and the sexual partner should also be treated. Long-term treatment may cause invasion of other bacteria not sensible to the drug. If suprainfection occurs, the treatment with Melioeko should be discontinued.

**Taking other medicines**

Please, tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Melioeko if you are prescribed another drug during treatment. It is particularly important to inform your doctor that you are taking blood-thinning medicines (anticoagulants) such as warfarin or acenocoumarol.

**Pregnancy and breastfeeding**

Consult with your doctor or pharmacist before using this drug during pregnancy or breastfeeding.

During pregnancy, especially in the first trimester, it should not be prescribed.

**Important information about some of the excipients of Melioeko**

This cream contains benzoic acid, which is mildly irritant to the skin, eyes and mucous membranes.

**3. HOW TO USE MELIOEKO**

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The cream is inserted deeply into the vagina through the applicator, best done in the reclining position. 1 fulfilled applicator, every evening at bedtime for fifteen consecutive days is used. At the same time the sexual partner must also be treated.

The treatment should be continued even if any of the symptoms (itching, vaginal discharge) disappears, in order to prevent any possible recurrence.

**If you use more Melioeko**

If you use more Melioeko than you should, or if the children take it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

**If you forget to use Melioeko**

If you forget a dose (or more doses), use the next dose when it is time to use it usually.

Do not use a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all other medicines, Melioeko may cause side effects, although not everybody manifests them. Sometimes they may be serious, sometimes not. Do not worry about this list of possible side effects. None of them may appear to you.

In the beginning of the treatment you might notice: vaginal burning sensation, irritation, pelvic cramps, exanthema and headache. In this case the treatment should be discontinued and another appropriate treatment should be initiated.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **5. HOW TO STORE MELIOEKO**

Keep out of the reach and sight of children!

Do not use Melioeko after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light.

#### **6. FURTHER INFORMATION**

##### **What Melioeko 1% cream contains**

**The active substance** is econazole nitrate.

1 g cream contains 10 mg econazole nitrate.

**The excipients** are: macrogol stearate, macrogol glycerol oleate, liquid paraffin, essence lavandule, benzoic acid, diethylene glycol monoethyl ether, purified water.

##### **Content of the pack**

Carton box with 1 tube of 30 g, with applicator.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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