

PACKAGE LEAFLET: Information for the patient

MELIOEKO

Ovules – 150 mg

(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:

1. What Melioeko ovules are and what are they used for
2. Before you use Melioeko ovules
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1. WHAT MELIOEKO OVULES ARE AND WHAT ARE THEY USED FOR

Melioeko ovules contain the active substance econazole nitrate, which is an imidazole derivative with antifungal activity. It is active 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 synthesis of membrane. Resistance occurs rarely.

Econazole nitrate absorption is small when it is used on the skin or intravaginally.

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

elimination.

Melioeko is indicated for the treatment of vaginitis due to *Candida albicans* and other yeasts.

2. BEFORE YOU USE MELIOEKO OVULES

Do not use Melioeko if you:

- have known hypersensitivity to econazole nitrate or to any imidazole derivative antifungal agent and also to any of the excipients of the ovule;
- are under 16 years old.

Take special care with Melioeko

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

During the treatment of genital areas, it is preferable that also the sexual partner has a topical treatment cycle for preventive purpose.

You should be sure not to infect the others; do not allow the others to use your towel.

Melioeko may cause burning sensation and irritation. Cases when irritation appears indicate hypersensitivity reaction and in this case the treatment should be discontinued.

Long-term treatment may cause invasion of other bacteria not sensible to the drug. If suprainfection occurs, the treatment with Melioeko should be discontinued and another appropriate treatment may be initiated.

Taking other medicines

Concomitant treatment with other drugs can affect or be affected by Melioeko.

Please, tell your doctor or pharmacist if you are taking, have recently taken other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Melioeko-ovules if you are given another drug during treatment.

It is particularly important to inform your doctor that you are taking medicines to thin the blood (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 or breast-feeding, vaginal ovules should be used only in cases where it is very necessary and under the direct control of the doctor.

3. HOW TO USE MELIOEKO OVULES

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

Ovules are inserted high into the vagina, best done in the reclining position, 1 ovule every evening, at bedtime for three consecutive days. In event of relapse, a second round of treatment should be undertaken.

If you use more Melioeko

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

If swallowed, nausea, vomiting, diarrhea may occur which may need symptomatic treatment.

If you forget to use Melioeko

If you forget to use one dose, use the next dose at its usual time. Do not use a double dose to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Melioeko may cause side effects, although not everybody gets 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.

Very common or common side effects ($\geq 1/10$); ($\geq 1/100$ to $<1/10$):

- Skin reactions.

Uncommon side effects ($\geq 1/1,000$ to $< 1/100$):

- Vaginal burning.

Frequency unknown:

- Angioedema.

In the beginning of treatment, other undesirable effects may also occur such as: pelvic cramps, exanthema and headache. In these cases 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 OVULES

Keep this medicine out of the sight and reach of children.

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

Do not store above 25°C!

Keep in the original package to protect them from light.

6. FURTHER INFORMATION

What Melioeko ovules contain

The active substance is econazole nitrate.

1 ovule contains 150 mg econazole nitrate.

The excipient is: hard fat.

Contents of the pack

Box with 5 ovules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.