

PACKAGE LEAFLET: Information for the patient

MELIORA

Ovules – (200 mg / 500 mg / 660,000 I.U. / 15 mg)

(Chloramphenicol, Metronidazole, Nystatin, Hydrocortisone acetate)

Read 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 s of illness are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Meliora is and what it is used for
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1. WHAT MELIORA IS AND WHAT IT IS USED FOR

Meliora contains the active substances chloramphenicol, metronidazole, nystatin and hydrocortisone acetate.

Meliora is used to treat or to prevent the vaginal s and of the cervix caused by certain microorganisms.

Indications:

- treatment of vaginitis and cervicitis caused by aerobic and anaerobic bacteria (including *Clostridium spp*), and by Gram-positive or Gram-negative organisms;

- treatment of vaginitis and cervicitis caused by *Trichomonas vaginalis* in combination with other types of microorganisms;
- treatment of vaginitis and cervicitis caused by *Mycoplasma spp* or *Chlamydia spp* in association with other microorganisms;
- treatment of mycotic vaginitis caused by *Candida* in combination with other types of microorganisms;
- treatment of mixed vaginitis caused by the association bacteria, *Trichomonas vaginalis*, *Candida spp* and *Mycoplasma spp* or *Chlamydia spp*;
- prevention of vaginitis and cervicitis for women undergoing with immunosuppressive therapy, chemotherapy or corticosteroids and for women undergoing radiotherapy;
- prevention of vaginitis and cervicitis in patients who will be subjected to exploratory or surgical intervention in the genital area (hysterosalpingography, tubal surgery, endometrial biopsy etc.);
- treatment of pathogenic flora before harvesting smear for PAP - test to clarify the microscopic field and to improve interpretation cytotest.

Meliora ovules are indicated to be used in the adult females. If necessary, Meliora can also be administered to adolescents.

2. BEFORE YOU USE MELIORA

Do not use Meliora if you:

- are allergic to any of the active substances or excipients of Meliora;
- have severe liver or renal failure;
- have severe hematologic disorders;
- are pregnant or breastfeeding.

Take special care with Meliora

Ask your doctor before you use Meliora.

If you have a history of hematologic disorders or follow a prolonged treatment, it is recommended to perform regular blood tests, especially complete blood count. Although there

have not been reported such reactions for this medicine, the treatment should be stopped if any possible decrease in erythrocytes, leukocytes and platelets occurs.

Prolonged treatment is followed by side effects such as central or peripheral neuropathy (paraesthesia, ataxia, vertigo, epileptic seizures). Although there have not been reported such reactions for this medicine, the treatment should be discontinued in cases of ataxia, vertigo or confusion.

This medicine should be used with caution in patients with severe chronic or progressive central and peripheral neurological disorders because of their worsening.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with product containing metronidazole. If you are affected by Cockayne, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards. Tell your doctor immediately and stop taking metronidazole if you develop: stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

Do not drink alcohol or do not use drugs containing alcohol during treatment with Meliora (see section “Taking other medicines”).

It is not recommended to do more than 2 – 3 courses of treatment per year.

The concomitant use of condoms or a diaphragm with Meliora - ovules may increase the risk of breaking the contraceptive device.

Taking other medicines

Inform your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines obtained without a prescription.

The systemic absorption of the active substances is reduced, hence the risk for interactions with other medicines is insignificant. However, precaution should be done with the following:

Alcohol: do not consume alcoholic beverages and drugs containing alcohol during treatment with Meliora and for at least 48 hours afterwards because of the possibility of a disulfiram-like reaction which can be manifested with flushing, vomiting, tachycardia etc.

Antianemic drugs: chloramphenicol may decrease the effects of iron and vitamin B₁₂ in anaemic patients.

Antiepileptics: metronidazole and chloramphenicol inhibit the metabolism of phenytoin (increased plasma concentration), while plasma concentrations of metronidazole and chloramphenicol are decreased by phenobarbital, with a consequent reduction in their effectiveness.

Cyclosporin: risk of elevation of cyclosporin serum levels; serum cyclosporin and serum creatinine should be closely monitored when of cyclosporin with metronidazole and chloramphenicol is necessary.

Cytotoxics: plasma levels of busulfan may be increased by metronidazole, which may lead to severe busulfan toxicity; metronidazole inhibits the metabolism of fluorouracil (increased toxicity).

Disulfiram: psychotic reactions have been reported in patients who were using metronidazole and disulfiram concurrently.

Lithium: plasma levels of lithium may be increased by metronidazole. Plasma concentration of lithium, creatinine and electrolytes should be monitored in patients under treatment with lithium while they receive metronidazole.

Oral anticoagulants (warfarin type): metronidazole and chloramphenicol enhance the anticoagulant effect of warfarin and increase the hemorrhagic risk caused by decreased hepatic catabolism. In this case, prothrombin time should be more frequently monitored and anticoagulant therapy adjusted during treatment with Meliora.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this medicine.

Meliora should not be used during pregnancy unless the doctor considers absolutely necessary its use.

Meliora should not be used during breastfeeding. If your doctor believes that the initiation of treatment is absolutely necessary, you should discontinue breastfeeding.

Driving and using machines

Meliora has no effect on the ability to drive or use machines.

3. HOW TO USE MELIORA

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure for its use.

If you think that the effect of treatment with Meliora is too strong or too weak, ask your doctor or pharmacist.

Meliora ovules are for intravaginal use.

The ovule should be inserted deep inside the vagina, sitting relaxed in a prone position.

The usual dose is one ovule per day, at bedtime. The duration of treatment is 12 days.

In case of ulcerative cervicitis, the treatment will be repeated 1 – 2 times, until the complete healing, with a break of 7 days between each treatment course.

In case when cervicitis and vaginitis are accompanied by severe inflammation caused by infections (pelvic congestion, metro-adnexitis, pelvic peritonitis), your doctor may recommend the combination of Meliora with systemic antibiotics.

Meliora should not be used in pediatric population.

If it is necessary the use in adolescents, the doses are the same as for adults.

The duration of treatment with Meliora will be determined by your doctor depending on the periodic evaluation of the improvement of your condition.

If you use more Meliora than you should

If you use more Meliora than you should, contact your doctor to seek advice on the risk and the

appropriate measures.

If you forget to use Meliora

Do not use a double dose to make up the forgotten dose.

If you stop using Meliora

Keep using Meliora till the end of the treatment, as long as your doctor has recommended you.

Each dose is necessary to improve or to treat the condition.

There are no special cases reported which may result in an immediate termination of the treatment.

If you have further questions about this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Meliora can cause side effects, although not everybody gets them.

The risk of side effects is negligible due to the reduced absorption of active substances.

Erythema, local burning, pelvic discomfort, vulvovaginal candidiasis, vulvovaginal disorders, menstrual cycle irregularities, vaginal haemorrhage, gastrointestinal disturbances with nausea and unpleasant metallic taste can occur especially with the prolonged use and after the first dose. Hypersensitivity reactions including rashes, fever and angioedema may also occur.

If you get these side effects or any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE MELIORA

Keep this medicine away from children!

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

Do not store above 25°C!

Keep in the original package.

6. OTHER INFORMATION

What Meliora ovules contain:

The **active substances** are: chloramphenicol, metronidazole, nystatin and hydrocortisone acetate.

Each ovule contains 200 mg chloramphenicol, 500 mg metronidazole, 660,000 I.U. nystatin and 15 mg hydrocortisone acetate.

Excipients: hard fat.

Content of the pack

Carton box with 12 ovules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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