

PACKAGE LEAFLET: Information for the user

MELIOZOL

Ovules – 500 mg

(Metronidazole)

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

Meliozol ovules contain the active substance metronidazole. Metronidazole, a synthetic derivative of nitroimidazole, acts against gram-positive and gram-negative anaerobic microorganisms (*Bacteroides* species, including the *B.fragilis* bacterial group, *Clostridium* species, *Eubacterium* species, *Peptococcus* species, *Peptostreptococcus* species and against protozoan (*Trichomonas vaginalis*, *Entamoeba histolytica*, and *Giardia lamblia*). The mechanism of action of metronidazole is not yet clear. It is thought that metronidazole inhibits the synthesis of DNA. It has bactericidal action.

Meliozol ovules are used in:

- female urogenital trichomoniasis (*Trichomonas vaginalis*);
- bacterial vaginosis (also known as non-specific vaginitis, anaerobic vaginosis or *Gardnerella* vaginitis).

Your doctor may have given you Meliozol for another purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU USE MELIOZOL OVULES

Do not use Meliozol ovules if you suffer from hypersensitivity to metronidazole, to any of the other nitroimidazole derivatives or to any of the excipients of the ovule.

Take special care with Meliozol ovules

You should not consume alcoholic beverages during treatment with metronidazole and for at least 48 hours after the end of treatment because there is a risk of disulfiram-like reaction.

Meliozol should be used with caution in active diseases of the central nervous system, except for brain abscess, in patients that are having kidney dialysis and those that have blood disorders.

Also care should be taken in patients with impaired liver function, during pregnancy and breast-feeding.

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 syndrome, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards.

Tell your doctor immediately and stop using metronidazole if you develop:

stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic-coloured stools or itching.

Special patient monitoring is advised if the treatment continues for more than 10 days.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Meliozol ovules.

Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Meliozol if you take any other medicine during treatment.

- When given with alcohol, metronidazole may provoke a disulfiram-like reaction in some patients.
- During concomitant use of disulfiram with metronidazole, acute psychosis or confusion were observed.
- It is reported a metabolism or excretion impairment of many drugs including: warfarin, phenytoin, lithium, busulphan and fluorouracil causing an increased incidence of side effects.
- It is thought that phenytoin may accelerate the metabolism of metronidazole.
- Metronidazole plasma concentrations are reduced from phenobarbital, causing a reduction in the efficacy of metronidazole.
- Cimetidine increases the plasma concentrations of metronidazole and may increase the risk of neurological side effects as a result of treatment with metronidazole.

Pregnancy

Tell your doctor or pharmacist if you are pregnant or are planning to have a baby.

Metronidazole is mutagenic in bacteria and carcinogenic in rodents. It readily crosses the placenta achieving similar concentrations with the rest of the body. For this reason its use in pregnancy is opposed.

Breastfeeding

Metronidazole is excreted into breast milk giving it a bitter taste which may impair baby's feeding. It is recommended to stop breast-feeding for 12 to 24 hours when the mother is treated with a single-dose of metronidazole, while no specific recommendations are given for long-term treatment.

Driving and using machines

While using Meliozol ovules you may experience: dizziness, drowsiness, confusion, seizures, and visual disturbances. If this happens, do not drive or use any machinery or tools.

3. HOW TO USE MELIOZOL OVULES

Always use Meliozol ovules as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 or 2 ovules per day and 5 oral tablets.

If you use more Meliozol ovules than you should

If you accidentally use an overdose of Meliozol, tell your doctor immediately or contact the nearest hospital.

If you forget to use Meliozol ovules

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

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

4. POSSIBLE SIDE EFFECTS

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

Metronidazole is well tolerated in the recommended doses. Tell your doctor about the following side effects that may occur:

- mild gastrointestinal disorders (nausea, vomiting, abdominal pain, metallic taste, dry mouth, diarrhoea);
- hypersensitivity reactions (angioedema, eczema, urticaria, severe skin reactions) are rare;
- neurological adverse reactions (headache, dizziness, drowsiness, ataxia, seizures, encephalopathy, peripheral neuropathy, cerebellar syndrome, confusion, nerve disorders, psychotic disorders, hallucinations, depression);
- darkening of urine;
- visual disturbances;
- hearing impairment, ringing in the ears (tinnitus);
- inflammation of the mucous membranes (mucositis);

- transitional neutropenia;
- appetite decreased;
- pancreatitis, hepatic disorders, which may appear in very rare cases;
- pancytopenia, agranulocytosis, thrombocytopenia and leucopenia;
- muscles pain, asthenia;
- aseptic meningitis;
- vaginal ovules can cause mild irritation of the vaginal mucosa, whereas gastrointestinal disorders are very rare.

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.

When any of the above-mentioned side effects appears, the treatment with Meliozol should be discontinued and you should consult your doctor or pharmacist.

5. HOW TO STORE MELIOZOL OVULES

Keep out of the sight and reach of children!

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

Do not store above 25°C!

Keep in the original package to protect from light and humidity.

6. FURTHER INFORMATION

What Meliozol 500 mg ovules contain

The active substance is metronidazole.

Each ovule contains 500 mg metronidazole.

The excipients are: colloidal anhydrous silica and hard fat.

Contents of the pack

Box with 10 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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