

PACKAGE LEAFLET: INFORMATION FOR THE USER

Δ MEDAZOL

500 mg vaginal tablet

METRONIDAZOLE

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

• *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 you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

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2. Before you take Medazol
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1. WHAT MEDAZOL IS AND WHAT IT IS USED FOR

MEDAZOL vaginal tablets contain a medicine called metronidazole. This medicine belongs to the group of antibiotics.

MEDAZOL vaginal tablets work by destroying bacteria and parasites that cause infection in your body.

MEDAZOL vaginal tablets are used in the treatment of:

- bacterial vaginitis caused by Gardnerellom vaginalis
- trichomoniasis caused by Trichomonas vaginalis.

If you need more information about your illness, you should consult with your doctor.

2. BEFORE YOU TAKE MEDAZOL

Do not use MEDAZOL vaginal tablets:

- If you are allergic to the active substance or any of the other ingredients of this medicine (see section 6).

Signs of allergy can include hives, difficulty swallowing or breathing problems, swelling of the lips, face, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before using MEDAZOL vaginal tablets.

Be especially careful before applying MEDAZOL vaginal tablets if you:

- have or have ever had problems with your liver
- go to hemodialysis for renal failure (see section 3)
- have a disease of the nervous system.

If you are not sure whether any of the above applies to you, please contact your doctor.

Taking other medicines with MEDAZOL vaginal tablets

Tell your doctor if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.

MEDAZOL vaginal tablets can have an impact on the action of some other medicines, while some other medicines may have an impact on the action of MEDAZOL vaginal tablets.

Tell your doctor if you are taking:

- Blood thinners such as warfarin
- lithium for the treatment of mental diseases
- Phenobarbital or phenytoin for epilepsy
- 5-fluorouracil for the treatment of tumors
- Busulfan for treatment for leukemia (blood cell tumor)
- Cyclosporine, which is used to prevent the rejection of transplanted tissues and organs
- Disulfiram to treat alcoholism.

Taking food and drinks during the administration of MEDAZOL vaginal tablets

Do not consume alcoholic beverages during therapy with MEDAZOL vaginal tablets, nor for the next 48 hours after the completion of therapy. Alcohol consumption during therapy with MEDAZOL vaginal tablets can have unpleasant side effects such as nausea, vomiting, abdominal pain, heat, and redness of the face, rapid or uneven heart beat and headaches.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, you think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

MEDAZOL vaginal tablets should not be taken during pregnancy, unless it is determined by a doctor that is necessary.

MEDAZOL vaginal tablets should not be taken during breast-feeding, because small amounts of the medicine are excreted into mother's milk.

Driving and using machines

Δ Trigonin, a medicine with the possible influence of the psychophysical abilities (attention when managing motor vehicles and machines).

MEDAZOL vaginal tablets can cause drowsiness, dizziness, confusion, hallucinations, seizures, or temporary difficulties with vision problems (such as blurred or duplicate of vision).

Do not drive or use machines if you experience some of the listed side effects.

3. HOW TO USE MEDAZOL

Always take this medicine exactly as your doctor has told you.

Check with your doctor, if you are not sure.

Treatment of bacterial vaginitis and trichomoniasis

Both partners should be treated at the same time.

MEDAZOL vaginal tablets shall be applied during 10 days.

Every night, insert one MEDAZOL vaginal tablet deep in the vagina previously soaked in water for a few seconds.

In case of any questions regarding the use of this medicine, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop applying MEDAZOL vaginal tablets and contact your doctor or go to the nearest emergency room if:

- you notice a swelling of arms, legs, ankles, face, lip, pharynx (which may cause difficulty swallowing), hives or skin rash. All of the above may indicate an allergic reaction to MEDAZOL vaginal tablets.
- you have an elevated body temperature, stiff neck, headache, hallucinations (the illusion of things or sounds which in reality are not there), problems with the movement of arms and legs, problems with speech or the feeling of confusion (confusion). All of the above can be indicative of a serious but very rare side effect of brain disease (encephalopathy).

Tell your doctor immediately if you notice any of the following side effects:

- yellow color of the skin and the whites of the eyes. This can be due to liver problems (jaundice).
- unexpected infections, sores in the mouth, bruising, bleeding of the gums or express tiredness. This can be a result of a disturbance in the blood.
- extreme abdominal pain, which can pass to back pain. This can be the result of inflammation of the pancreas (pancreatitis).

While taking MEDAZOL vaginal tablets the following side effects were reported:

Very rare:

- cramps
- mental disorders, such as feelings of confusion (confusion), or a hallucination (the illusion of things or sounds which in reality there is no)
- problems with vision, such as blurred vision or duplicate images
- skin rash, redness, and heat of the face
- headache
- the darker the color of urine
- drowsiness or dizziness
- pain in the muscles and joints.

Not known:

- numbness, tingling, pain or a feeling of weakness in the hands or feet
- an unpleasant taste in the mouth
- the feeling of Hairy tongue
- nausea, vomiting, abdominal discomfort, abdominal pain or diarrhea
- loss of appetite
- fever
- the feeling of depression
- pain in the eyes (optic neuritis)

- a group of symptoms that are manifested together: elevated body temperature, nausea, vomiting, headache, a stiff neck and pronounced sensitivity to strong light. All of these symptoms can be the result of inflammation of the meninges and spinal cord the meninges (meningitis)
- irritation of the vagina (as a local reaction at the application site).

The following classification was used for the display of the frequency of side effects:

Very often: it can affect more than 1 in 10 patients.

Common: it can affect up to 1 in 10 patients.

Uncommon: it can affect up to 1 in 100 patients.

Rare: it can affect up to 1 in 1000 patients.

Very rare: it can affect up to 1 in 10000 patients.

The unknown: cannot be estimated from the available data.

If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE MEDAZOL

Keep out of reach and sight of children.

The medicinal product must be stored at temperature below 25 °C

Shelf-life:

Expiry date is printed on the packaging.

Shelf life is 5 years from the date of manufacture indicated on the packaging.

The medicine should not be used after the expiry date.

Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. Such behavior will protect environment.

6. FURTHER INFORMATION

The active substance in MEDAZOL vaginal tablets is metronidazole.

One MEDAZOL vaginal Tablet contains 500 mg of metronidazole.

The other ingredients are: lactose monohydrate; povidone; cellulose, microcrystalline; carmellose sodium, networked; TALC; magnesium stearate.

How MEDAZOL looks like and contents of the Pack

MEDAZOL 500 mg vaginal tablets are white, almond-shaped.

10 vaginal tablets in PVC/Al blister, in a box.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

BELUPO lijekovi i kozmetika, d.d.

Ulica Danica 5

48 000 Koprivnica, Croatia

Manufacturer of the medicinal product

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