

PACKAGE LEAFLET: INFORMATION FOR THE USER

ROJAZOL

200 mg pessary

MICONAZOLE

• 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?

1. What Rojazol is and what it is used for
2. Before you take Rojazol
3. How to take Rojazol
4. Possible side effects
5. How to store Rojazol
6. Further information

1. WHAT ROJAZOL IS AND WHAT IT IS USED FOR

Miconazole pessary is gynecological anti-inflammatory medicine and an antiseptic, derivative of imidazole group of medicines.

ROJAZOL pessaries are used to treat infections of the vagina. These infections include itching, redness and white discharge.

ROJAZOL pessaries are destroying fungi that cause infection, as well as some of the bacteria that may also be present.

Maybe it will be your sexual partner also needs to heal. For advice, please ask your doctor.

2. BEFORE YOU TAKE ROJAZOL

Do not use ROJAZOL pessaries:

- If you are allergic to miconazole or any of the other ingredients of the medicinal product (listed in section 6).

Warning and precautions

Contact your doctor or pharmacist before using ROJAZOL pessaries if you are using "mechanical" contraception, including condoms or diaphragm. ROJAZOL can damage the condom and disable the contraception. Consult your doctor about other methods of birth control while using ROJAZOL pessaries.

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

Children

Do not use ROJAZOL pessaries in children.

Other medicines and ROJAZOL pessaries

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

In patients taking medicines to thin the blood, e.g. warfarin, caution should be exercised and effect of anti-coagulation should be controlled.

Also, be sure to tell your doctor if you are taking:

- medicines for the treatment of diabetes
- medicines for the treatment of epilepsy (e.g., phenytoin)
- medicines for lowering blood fat (for example, simvastatin, lovastatin)
- medicines used to treat high blood pressure (e.g., dihydropyridine, verapamil).

Pregnancy and breastfeeding

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

With the approval of your doctor, you will be able to use ROJAZOL pessaries.

Driving and using machines

It is not expected that ROJAZOL pessaries have an impact on the ability to drive and use machines.

3. HOW TO TAKE ROJAZOL

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The use of pessary:

- Do not swallow the pessary
- Use pessary before going to sleep. In this way pessary remains in place.

Inserting pessary:

- Wash your hands with warm water and soap
- Remove the pessary from envelope
- Lie on your back with your legs bent and spread the knees
- With your middle finger insert pessary as deep as possible into the vagina.

After inserting always wash your hands with warm water and soap. Other people must not use your towel as they could get infected.

After inserting a pessary in the vagina it may melt and drip. It will not stain the skin and clothes, but you may need to use a sanitary pad.

The duration of treatment

ROJAZOL pessaries are used during 7 consecutive days.

Do not stop treatment even though the itching, white discharge and other signs of inflammation are retreating after a few days. Do not stop treatment during menstruation.

If you forget to take ROJAZOL pessary

If you forget to take pessary, use the next dose at the usual time and continue the treatment according to the schedule.

If a person swallows ROJAZOL pessary

In case of accidental ingestion of pessary ROJAZOL there will be no harmful effect on health, but you can contact a doctor for advice.

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

4. POSSIBLE SIDE EFFECTS

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

During the administration of this medicine, possible side effects are:

Very rare:

- allergic reactions
- vaginal irritation of mucous membranes, for example. Mild transient redness, itching and burning sensation and therefore you do not need to interrupt treatment.

The following classification was used to display 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 ROJAZOL

Store below 25 ° C.

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

Shelf-life of the medicine is 2 years from the production date indicated on the packaging.

Do not use this medicine after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to preserve the environment.

6. FURTHER INFORMATION

What ROJAZOL pessaries contain

The active substance is miconazole nitrate. One pessary contains 200 mg of miconazole nitrate.
Excipient is solid fat.

How ROJAZOL pessaries look like and contents of the Pack

ROJAZOL pessaries are white in color. 7 (1 x 7) pessary in the Al/PE Strip, 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

BELUPO lijekovi i kozmetika, d.d.
Ulica Danica 5
48 000 Koprivnica, Croatia