

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Preparation name:

Gyno Pevaryl® 150

Vaginal Ovules

Composition:

Each vaginal ovule contains:
Econazole nitrate 150 mg

Inactive and allergenic ingredients in the preparation - see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in men. This medicine is not intended for young girls and adolescents under 16 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for local treatment of fungal infections in the vagina.

Therapeutic group:

Antifungals

2. BEFORE USING THE MEDICINE

Do not use the medicine

- If you are sensitive (allergic) to the active ingredient, to any of the other ingredients contained in the medicine or to other antifungals from the same family.

For the list of additional ingredients, see section 6 "Further information".

- If you are younger than 16.

Special warnings regarding use of the medicine

This medicine is intended for external (vaginal) use only.

Do not swallow the medicine.

During the course of treatment, avoid use of contraceptives such as a diaphragm or condom made of latex, since their effectiveness may be damaged. In addition, consult the doctor regarding use of spermicides, since their effectiveness may be damaged during the course of treatment. Consult the doctor or pharmacist regarding use of other contraceptives. Do not concomitantly use the medicine with another internal or external treatment (applied or inserted) of the genitals.

If there is significant irritation or hypersensitivity, stop the treatment.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:

Warfarin and acenocoumarol (to treat coagulation problems).

The doctor will check if the anticoagulant is working properly.

Pregnancy and breastfeeding

Before using the medicine, inform the doctor if you are pregnant, may be pregnant or may become pregnant, or are breastfeeding.

You may be able to use the medicine, only if the doctor thinks you need the medicine and only with his authorization.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally

One ovule in the evening at bedtime, for 3 consecutive evenings.

Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external (vaginal) use only.

If the medicine is mistakenly swallowed, refer to the doctor immediately.

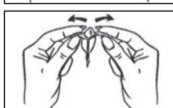
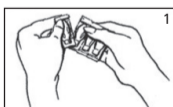
Attention:

Instructions for use

1. First, wash your hands. Insert one ovule, using the enclosed applicator, deep into the vagina at bedtime. The best way to do this is while lying down. If you are pregnant, check with the doctor if you should use the applicator to insert the medicine.

Instructions for use of the applicator:

2. Each ovule is individually wrapped in a separate packet to protect it and keep it clean. To remove an ovule from its packet, separate one packet by tearing along the perforated line between two packets and then remove the ovule from its plastic packet by pulling away the tabs at the upper part (Fig. 1).



3. Pull out the plunger from the white plastic applicator until it stops. Gently insert the ovule into the applicator (Fig. 2). Be especially careful when handling an ovule that softened as a result of being kept at a high temperature.



4. Lie down on your back with your knees bent and spread apart. Gently insert the applicator with the ovule deep into the vagina, as far as you can without using force or causing discomfort. Press on the plunger to release the ovule and then remove the applicator (Fig. 3). Wait a few minutes before getting up from the lying position.



5. Wash the applicator and your hands with soap and hot water.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember; but never take two doses together.

How can you contribute to the success of the treatment?

Complete the treatment recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Only wear cotton underwear and change them often. Stockings should also be changed daily.

Your partner may become infected; therefore, be sure to avoid intercourse or use of a condom (that is not made of latex) during intercourse, during the entire treatment period. It is also recommended to consult the doctor regarding the need for drug treatment for your partner as well.

If you are using a vaginal douche preparation between treatments, be sure not to insert the rinsing fluid too forcefully and at too large a quantity, so as not to inject the fluid into the uterus - which may transfer the infection there.

Underwear may become stained when using the medicine. To avoid staining, a sanitary pad or panty liner can be used.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Gyno Pevaryl may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment and refer to a doctor immediately if you experience any of the following signs:

Sudden swelling of the face or throat, skin rash (urticaria), severe irritation, burning sensation, severe redness or severe blisters on the skin. These can all be signs of a severe allergic reaction (occurs rarely, in less than 1 in 10000 patients).

You may need immediate medical treatment.

Additional side effects:

Common side effects:

Itchy skin
Burning sensation on the skin

Uncommon side effects:

Rash
Burning sensation inside the vagina

Rare side effects:

Local side effects in the skin or vagina after administration, such as: redness.

Side effects of unknown frequency:

Sensation of swelling, pain and itch in the vaginal area
Contact dermatitis
Peeling skin

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general wellbeing, consult the doctor immediately.

Reporting side effects

Side effects can be reported to the Ministry of Health via the online Side Effects Reporting Form that can be found on the Ministry of Health homepage <http://www.health.gov.il> or via the following link:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Do not store above 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains Hard Fat.

What the medicine looks like and the contents of the package: a torpedo-shaped, white to off-white vaginal ovule. Each box contains 3 vaginal ovules and an applicator.

Registration Holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel. Manufacturer and address: Janssen Pharmaceutica N.V., Beerse, Belgium.

This leaflet was checked and approved by the Ministry of Health on 04.11.2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 043-50-26137-01