

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gyno-Pevaryl® 150mg vaginal pessaries

Econazole nitrate

Gyno-Pevaryl is a registered trademark

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

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1. What Gyno-Pevaryl 150 pessaries are and what they are used for

The name of your medicine is Gyno-Pevaryl 150mg vaginal pessaries. They are called 'Gyno-Pevaryl 150 pessaries' in this leaflet. This pack contains 3 pessaries.

Gyno-Pevaryl 150 pessaries are solid, torpedo-shaped pessaries (vaginal suppositories). When inserted into the vagina they release a medicine called econazole nitrate. This belongs to a group of medicines called 'antifungals'.

Gyno-Pevaryl 150 pessaries are used for infections of the vagina and the skin around the vagina. The infections are caused by fungi and yeasts such as thrush (*Candida*).

2. What you need to know before you use Gyno-Pevaryl 150 pessaries

Do not use Gyno-Pevaryl 150 pessaries if:

- You are allergic to econazole nitrate or any of the other ingredients of this medicine (listed in section 6)
- You are allergic to any other medicine used to treat thrush or other fungal infections
- You are under 16 years old

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Gyno-Pevaryl 150 pessaries.

Warnings and precautions

Talk to your doctor or pharmacist before using Gyno-Pevaryl 150 pessaries if:

- You are using other treatment for your vagina.

Talk to your doctor about using another type of contraception while you are using this medicine if:

- You are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Gyno-Pevaryl 150 pessaries can damage the rubber and stop them working properly.
- You are using a spermicidal contraceptive

Other medicines and Gyno-Pevaryl 150 pessaries

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular tell your doctor if you are taking:

- Medicines to thin the blood (anticoagulants) such as warfarin or acenocoumarol. Your doctor may check that the anticoagulant is working properly.

Pregnancy and breast-feeding

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

You may still be able to use Gyno-Pevaryl 150 pessaries if your doctor thinks you need to.

3. How to use Gyno-Pevaryl 150 pessaries

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

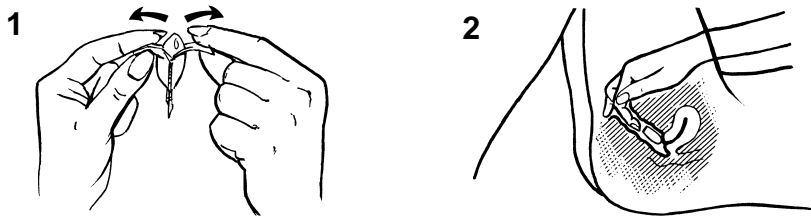
Using the pessaries

- Always wash your hands thoroughly before using this medicine. This is particularly important if you are pregnant
- The full course is 3 pessaries
- Use one pessary each day, for 3 days
- Use the pessary just before going to bed. This helps it to stay in place
- Do not swallow the pessary

Inserting the pessary

- Tear down the groove between two individually wrapped pessaries
- Remove one pessary from its plastic packet using the easy open tab (figure 1)
- Lie down with your knees bent and spread apart

- Push the pessary with your forefinger as far as you can into your vagina (figure 2)



When to stop using Gyno-Pevaryl 150 pessaries

Use the full course of 3 pessaries. Do this, even if the soreness, itching and discharge go away before the end of the course.

If you swallow Gyno-Pevaryl 150 pessaries

If a pessary is eaten or swallowed talk to a doctor or go to the nearest hospital casualty department straight away.

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

4. Possible side effects

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

Stop using Gyno-Pevaryl 150 pessaries and tell your doctor straight away if you notice the following. You may need urgent medical treatment.

- Sudden swelling of the face or throat. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction (affects fewer than 1 in 10,000 people)

Other side effects:

Common side effects (affects more than 1 in 100 patients)

- Itchy skin
- Burning sensation (skin)

Uncommon side effects (affects fewer than 1 in 100 patients)

- Rash
- Burning sensation (around or inside the vagina)

Rare side effects (affects fewer than 1 in 1000 patients)

- Reddening of your skin

Frequency unknown:

- Pain, swelling or irritation (around or inside the vagina)
- Inflammation of the skin (contact dermatitis)
- Peeling, flaky skin

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gyno-Pevaryl 150 pessaries

Keep this medicine out of the sight and reach of children. Store in the original container. Do not store above 30°C. Keep away from heat and sunlight.

Do not use Gyno-Pevaryl 150 pessaries:

- After the expiry date which is stated on the label. The expiry date refers to the last day of that month
- If the plastic packet is broken or missing
- If the pessaries are not white to off-white in colour

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gyno-Pevaryl 150 pessaries contain

The active substance is econazole nitrate. Each pessary contains 150 mg econazole nitrate.

The other ingredients are Wecobee M and Wecobee FS.

What Gyno-Pevaryl 150 pessaries looks like and contents of the pack

Gyno-Pevaryl 150 pessaries come in a plastic strip containing 3 pessaries. The pessaries are torpedo-shaped and white to off-white in colour.

Marketing Authorisation Holder:

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