

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gyno-Pevaryl® cream

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

1. What Gyno-Pevaryl is and what it is used for
2. What you need to know before you use Gyno-Pevaryl
3. How to use Gyno-Pevaryl
4. Possible side effects
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1. What Gyno-Pevaryl is and what it is used for

The name of your medicine is Gyno-Pevaryl cream. It is called 'Gyno-Pevaryl' in this leaflet.

Gyno-Pevaryl contains a medicine called econazole nitrate. This belongs to a group of medicines called 'antifungals'.

Gyno-Pevaryl is used for infections caused by fungi and yeasts such as thrush (*Candida*).

- In women, it is used for infections of the vagina and the skin around the vagina
- In men, it is used for infections of the penis and the skin around the penis

Your sexual partner should also be treated. They may have the infection even if they have no symptoms. If they are not treated, they may give the infection back to you.

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

Do not use Gyno-Pevaryl 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.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if:

- You are using any other treatment for your genitalia (vagina or penis)

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 can damage the rubber and stop them working properly.
- You are using a spermicidal contraceptive

Other medicines and Gyno-Pevaryl

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 for advice before taking this medicine.

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

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

Gyno Pevaryl contains:

Gyno-Pevaryl contains Benzoic Acid (E210) and Butylated hydroxyanisole (E320):

- Benzoic Acid (E210) – This medicine contains 30 mg of benzoic acid in each 15 g tube or 60 mg of benzoic acid in each 30 g tube, which is equivalent to 2 mg/g cream. Benzoic acid may cause local irritation.
- Butylated hydroxyanisole (E320) - May cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Gyno-Pevaryl

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

Women - using the cream

- Always wash your hands thoroughly before using this medicine. This is particularly important if you are pregnant
- If you are pregnant, you should use Gyno-Pevaryl without an applicator
- Use the cream once a day just before going to bed
- The cream is used inside and outside of your vagina
- Place an applicatorful (about 5 g) of cream into your vagina
- Also lightly cover your vagina and the skin around your vagina with a thin, even layer of cream

- Keep using the cream for 14 days

Gyno-Pevaryl does not include a vaginal applicator. It can be bought separately at the chemist.

Men - using the cream

- Use the cream once a day
- Lightly cover the penis and the skin around the penis (including under your foreskin if you have one) with a thin, even layer of cream
- Keep using the cream for 14 days

When to stop using Gyno-Pevaryl

Keep using the cream until the course is finished (14 days). Do this, even if the soreness, itching and discharge go away before 14 days.

If you swallow Gyno-Pevaryl

If a large amount of cream 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 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

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Keep away from heat and sunlight.

Do not use Gyno-Pevaryl:

- After the expiry date which is stated on the label. The expiry date refers to the last day of that month
- If the tube seal is broken or missing
- If the cream is not white in colour or has become runny (liquefied)

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 protect the environment.

6. Contents of the pack and other information

What Gyno-Pevaryl contains

The active substance in Gyno-Pevaryl is econazole nitrate. The cream contains 1% econazole nitrate.

The other ingredients are Tefose 63, labrafil M 1944 CS, mineral oil, butylated hydroxyanisole (E320), benzoic acid (E210), purified water.

What Gyno-Pevaryl looks like and contents of the pack

The cream is white and comes in a 15 g or 30 g white and blue aluminium tube.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by:

Karo Pharma AB, Box 16184, 103 24 Stockholm, Sweden

Gyno-Pevaryl is made by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Middleton Close, Banbury, Oxfordshire OX16 4RS, UK.
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