

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gyno-Pevaryl® Once 150mg vaginal pessary

Econazole nitrate

Gyno-Pevaryl is a trademark

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to use Gyno-Pevaryl Once 150mg vaginal pessary carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if
 - your symptoms worsen or do not improve after 7 days
 - you have more than 1 of these infections within 6 months
- 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 Once is and what it is used for

The name of your medicine is Gyno-Pevaryl Once 150mg vaginal pessary. It is called 'Gyno-Pevaryl Once' in this leaflet.

Gyno-Pevaryl Once is a solid, torpedo-shaped pessary (vaginal suppository). When inserted into the vagina, it releases a medicine called econazole nitrate. This belongs to a group of medicines called 'antifungals'.

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

2 Before you use Gyno-Pevaryl Once

Do not use Gyno-Pevaryl Once 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 believe or suspect that your symptoms are not due to thrush (*Candida*)

- You think you may have a sexually transmitted disease. If so you should see your doctor or go to a Special (Genito-Urinary) Clinic
- Do not use this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist before using Gyno-Pevaryl Once.

Warnings and precautions

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

- You have any of the following:
 - abnormal or irregular vaginal bleeding
 - blood stained discharge
 - sores or blisters in or around the vagina
 - any tummy pain or pain on passing urine
- You are using any other treatment for your vagina
- You are under 16 years old or over 60 years old

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

Other medicines and Gyno-Pevaryl Once

Tell your 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 pharmacist 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 Once if your doctor thinks you need to.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

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

3 How to use Gyno-Pevaryl Once

Always follow the instructions exactly. Check with your pharmacist if you are not sure how to use this medicine.

Using the pessary

- 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 Once without the applicator or ask your doctor to insert it for you
- Use the pessary just before going to bed. This helps it to stay in place
- Do not swallow the pessary

Inserting the pessary with the applicator

- Remove the pessary from the plastic packet using the easy open tab
- Pull the plunger of the applicator out until it sticks
- Gently push the pessary into the cup. Do not force it because it might stick
- Lie down with your knees bent and spread apart. Insert the applicator high into your vagina, pessary first
- Push the plunger to release the pessary
- Remove the applicator and dispose of it safely in your household waste



Check with your doctor if:

- Your symptoms are still present after 7 days
- Your symptoms return within 4 weeks
- You have more than 1 of these infections within 6 months

If you swallow Gyno-Pevaryl Once

If the 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 pharmacist.

4 Possible side effects

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

Stop using Gyno-Pevaryl Once 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:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Gyno-Pevaryl Once

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

Do not use Gyno-Pevaryl Once:

- After the expiry date which is stated on the carton and plastic strip after EXP. The expiry date refers to the last day of that month
- If the plastic packet is broken or missing
- If the pessary is not light beige 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 Once contains

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

The other ingredients are polygel, colloidal anhydrous silica, hard fat (Witepsol H 19, Wecobee FS), stearyl heptanoate.

What Gyno-Pevaryl Once looks like and contents of the pack

Gyno-Pevaryl Once comes in a plastic strip containing one pessary. It is torpedo-shaped and light beige in colour. A plastic applicator is also provided.

Marketing Authorisation Holder:

Karo Pharma AB
Box 16184, 103 24 Stockholm, Sweden

Manufacturer:

Lusomedicamenta - Sociedade, Técnica Farmacêutica, S.A., Estrada
Consiglieri Pedroso, 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal

OR

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

This leaflet was last revised in May 2021.