

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pevaryl[®] 1% topical cream

Econazole nitrate

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 Pevaryl is and what it is used for
2. What you need to know before you use Pevaryl
3. How to use Pevaryl
4. Possible side effects
5. How to store Pevaryl
6. Contents of the pack and other information

1. What Pevaryl is and what it is used for

The name of your medicine is Pevaryl 1% topical cream. It is called 'Pevaryl' in this leaflet.

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

Pevaryl is used for skin infections caused by certain fungi and yeasts.

2. What you need to know before you use Pevaryl

Do not use Pevaryl:

- if you are allergic to econazole nitrate or any of the other ingredients of this medicine (listed in section 6).

Do not use this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before using Pevaryl.

Warnings and precautions

- Talk to your doctor or pharmacist before using Pevaryl if you have inflamed, red, dry and scaly skin (eczema)
- Keep this medicine away from your eyes and mouth. If you get any cream in your eyes, rinse with water straight away. Keep your eyes open when you rinse.

Other medicines and 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 or pharmacist for advice before using this medicine.

You may still be able to use 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.

Pevaryl contains benzoic acid (E210) and butylhydroxyanisole (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 and may increase jaundice (yellow of the skin and eye) in newborn babies (up to 4 weeks old).
- Butylhydroxyanisole (E210) - May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use Pevaryl

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

The recommended dose is:

Skin infections

- Use the cream **twice a day**
- Rub the cream gently into the affected skin
- Keep the affected area clean and dry

When to stop using Pevaryl

The usual treatment duration is 2 to 4 weeks.

Talk to your doctor if your symptoms have not improved after 4 weeks.

If you swallow 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 Pevaryl and tell your doctor straight away if you notice the following.

- Severe irritation or reddening of the skin, or other signs of allergy during the first few days of treatment. This only happens in a small number of people
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Skin rash or hives (also known as nettle rash or urticaria)
- Peeling or blistering of the skin

Other side effects:

Common (affects more than 1 in 100 patients)

- Itching or redness of the treated area. This is much milder than an allergic reaction. Tell your doctor or pharmacist if this feeling lasts for more than a few minutes or gets worse (rash, burning or swelling)
- Pain of the treated area

Uncommon (affects fewer than 1 in 100 patients)

- Redness or swelling of the treated area
- Discomfort of the treated area

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store 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 this medicine:

- 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)

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 Pevaryl contains

The active substance is econazole nitrate. Pevaryl contains 1% econazole nitrate.

The other ingredients are purified water, macrogols (PEG-6 and PEG-32) / glycol stearate, liquid paraffin, oleoyl macrogolglycerides, benzoic acid (E210) and butylhydroxyanisole (E320)

What Pevaryl looks like and contents of the pack

Pevaryl comes in an aluminium tube containing 15 g or 30 g of white cream.

Marketing Authorisation Holder:

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

Lusomedicamenta – Sociedade Técnica Farmacêutica S.A., Portugal

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