

Package leaflet: Information for the patient

Fenoximetylpenicillin EQL 800 mg film-coated tablets Fenoximetylpenicillin EQL 1 g film-coated tablets

phenoxymethylpenicillin potassium

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What [Invented name] is and what it is used for

The active substance in [Invented name], phenoxymethylpenicillin, is a penicillin (antibacterial medicine) that prevents the bacteria from building a normal cell wall. Without cell walls, the bacteria die fast.

[Invented name] is used to treat tonsillitis, tooth infections, pneumonia, sinus infections, infections in the ear (otitis), bacterial skin- and soft tissue infections (such as connective tissue infection and Borrelia infection).

2. What you need to know before you use [Invented name]

Do not use [Invented name]

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Invented name]

- if you are allergic (hypersensitive) to cephalosporins (another group of antibiotics)
- if you experience diarrhoea that last for a long time or is severe

If you experience sudden rash, fever and/or facial swelling, stop taking the medicine and contact your doctor immediately.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. [Invented name] may affect or be affected by other medicines containing the following active ingredients:

- Methotrexate (for tumours and certain diseases in the immune system)
- Probenecid (used to treat gout)

[Invented name] with food and drink

[Invented name] has the best effect when taken on an empty stomach or at least 1 hour before a meal or 2 hours after a meal.

Pregnancy and breast-feeding and fertility

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 taking this medicine.

Pregnancy

There are no known risks using [Invented name] during pregnancy.

Breast-feeding

Phenoxymethylpenicillin potassium passes into breast milk but is unlikely to affect nursing infants.

Driving and using machines

There are no known effects on the ability to drive or use machines.

3. How to use [Invented name]

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

The recommended dose is determined by the doctor who adjusts it individually for you. The dose depends on the infection type and body weight.

The tablet can be divided into equal doses.

If you use more [Invented name] than you should

If you have taken more [Invented name] than you should, or if a child has been taking [Invented name] by accident, please contact your doctor or hospital to get an opinion of the risk and advice on action to be taken.

If you forget to use [Invented name]

Do not take a double dose to make up for a forgotten dose.

If you stop using [Invented name]

Do not stop taking [Invented name] even if you feel better already after a few days. It is important to continue taking the medicine according to instructions from your doctor. If you stop to take [Invented name], some bacteria may survive, grow and cause the infection to recur.

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

4. Possible side effects

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

Common (may affect up to 1 in 10 people):

- Nausea
- Loose stools
- Skin rash

Uncommon (may affect up to 1 in 100 people):

- Fever
- Vomiting
- Stomatitis (infection of mouth)
- Inflammation of the tongue
- Indigestion
- Joint pain
- Hives (urticaria)
- Swelling of skin, red patches on the skin (erythema multiforme or exfoliative dermatitis). Exfoliative dermatitis is a serious skin condition (with symptoms as redness of the skin and skin peeling), contact your doctor or hospital.
- Increase in a type of white blood cells (eosinophilia)

Rare (may affect up to 1 in 1,000 people):

- Severe allergic reaction (anaphylactic reaction). Stop taking [Invented name] and contact your doctor

Very rare (may affect up to 1 in 10,000 people):

- Changes in blood count: Reduction in the number of red blood cells causing anaemia-like symptoms such as fatigue and fever (haemolytic anaemia).
Reduction in leucocytes increasing tendency to infections (leukopenia).
Reduction of platelets (thrombocytopenia).
Reduction in the number of white blood cells causing fever, infections symptoms such as sore throat or urinary problem (agranulocytosis).
These conditions may be serious. If you get fever consult your doctor immediately.
- Positive Coomb's test (test for haemolytic syndroms)
- Itching

Not known (frequency cannot be estimated from the available data):

- Severe diarrhoea (Pseudomembranous colitis)
- Fungal overgrowth in the oral cavity and genital area

If you experience prolonged or severe diarrhoea you should contact a doctor.

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

No special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

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 [Invented name] contains

- The active substance is phenoxymethylpenicillin potassium 800 mg or 1000 mg.
- The other excipients are:
 - Povidone (E1201)
 - Magnesium stearate (E470b)
 - Hypromellose
 - Titanium dioxide (E171)
 - Macrogol 400

What [Invented name] looks like and contents of the pack

800 mg: White to off-white, capsule-shaped filmcoated tablets, with break line and embossing P/0.8 on the same side.

1 g: White to off-white, capsule-shaped filmcoated tablets, with break line and embossing P/1.0 on the same side.

Pack size:

Tablets 800 mg: Aluminium–OPA/Alu/PVC blisters 20, 30, 40 and 100 tablets

Tablets 1 g: Aluminium–OPA/Alu/PVC blisters 20, 30, 40 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

EQL Pharma AB
Stortorget 1
222 23 Lund
Sweden

Manufacturer

Remedica Ltd
Aharnon Str., Limassol Industrial estate
3056 Limassol
Cyprus

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark: Phenoxymethylpenicillin EQL

Iceland: Phenoxymethylpenicillin EQL

Sweden: Fenoximetylpenicillin EQL

This leaflet was last revised in 2025-04-23