

Package leaflet: Information for the user

Phenoxymethylpenicillin 250mg Film-coated Tablets (Phenoxymethylpenicillin)

Read all of this leaflet carefully before you start taking 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 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 Phenoxymethylpenicillin Tablets are and what they are used for
2. What you need to know before you take Phenoxymethylpenicillin Tablets
3. How to take Phenoxymethylpenicillin Tablets
4. Possible side effects
5. How to store Phenoxymethylpenicillin Tablets
6. Contents of the pack and other information

1. What Phenoxymethylpenicillin Tablets are and what they are used for

Phenoxymethylpenicillin is an antibiotic (antibacterial medicine) for treating infections. It belongs to a group of antibiotics called “Penicillins”. Phenoxymethylpenicillin works by killing the bacteria that can cause infections. Phenoxymethylpenicillin can also be used to prevent infections.

Your doctor has prescribed Phenoxymethylpenicillin Tablets because it can treat a range of bacterial infections of the ear, throat, lungs, skin and soft tissues.

It may also be used to prevent infections such as

- rheumatic fever or chorea (infection of the nervous system) recurring
- infection in patients without a spleen (abdominal organ)
- to prevent pneumococcal infection (e.g. in asplenia and in patients with sickle cell disease).

2. What you need to know before you take Phenoxymethylpenicillin Tablets

Do not take Phenoxymethylpenicillin Tablets

- if you are allergic (hypersensitive) to phenoxymethylpenicillin or any of the other ingredients of Phenoxymethylpenicillin Tablets (see section 6 Contents of the pack and other informations).
- if you know that you are allergic to penicillin or any other penicillin- type reactions

Warning and precautions

Talk to your doctor, pharmacist or nurse before taking Phenoxymethylpenicillin Tablets:

- if you know that you are allergic to cephalosporins, or any other antibiotic or any of the ingredients in your medicine.
- if you suffer from kidney problems.
- if you suffer from liver problems.
- if you suffer any blood disorders.
- if you are pregnant, trying to become pregnant or breast-feeding.
- if you suffer from bronchial asthma or suffer from a tendency to develop allergic conditions such as hay fever or eczema.
- if you suffer with persistent diarrhoea or vomiting caused by stomach or intestinal problems or being sick, or are suffering from any gut disorder which may affect the way your body absorbs the medicine.
- if you have suffered severe diarrhoea following previous treatment with antibiotics.
- You are on a low potassium diet. Each Phenoxyethylpenicillin 250 mg tablet contains 28 mg of potassium. This potassium content needs to be taken into consideration by patients with kidney problems or patients on a controlled potassium diet.
- if you have severe illness.
- if you are on long term treatment with Penicillin.

Other Medicines and Phenoxyethylpenicillin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular tell your doctor if you are using the following:

- Uricosuric drugs (medicines used to treat gout (painful inflammation of the joints) and other conditions which require lowering of blood uric acid levels, e.g. probenecid and sulfinpyrazone).
- Anticoagulants (medicines that prevent the clotting of blood, e.g. warfarin, coumarin and phenindione).
- Potassium-sparing diuretics (medicines used to treat high blood pressure, water retention, or some heart, liver or kidney conditions, e.g. Amiloride, spiro lactone).
- Any other antibiotics (such as tetracycline, erythromycin, chloramphenicol, sulphonamide).
- Methotrexate (a medicine used to treat cancer, psoriasis (a chronic skin disease) and rheumatoid arthritis).
- Guar gum (a medicine used to treat some types of diabetes).
- Neomycin (anti-fungal).
- Phenoxyethylpenicillin tablets may reduce the efficacy of oral contraceptives (“the pill”). Your doctor or pharmacist will be able to advise you on whether additional contraceptive measures are necessary whilst taking Phenoxyethylpenicillin tablets, such as using a condom or a diaphragm with spermicide.

Please tell your doctor or pharmacist if you have recently been given or are due to receive a typhoid vaccination.

You should also note that if you test your urine for glucose using a non-enzymatic test, Phenoxyethylpenicillin Tablets may give a false positive result. Please ask your pharmacist for advice on this.

Long term treatment should be monitored as overgrowth of resistant organisms including *Pseudomonas* or *Candida* may occur.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Phenoxyethylpenicillin Tablets with food and drink

Phenoxymethylpenicillin Tablets are best absorbed when taken on an empty stomach.

Pregnancy and breast-feeding

The effects of phenoxymethylpenicillin in pregnancy have not been adequately studied. If you are pregnant or planning to become pregnant, inform your doctor immediately. Phenoxymethylpenicillin Tablets should be used during pregnancy only if your doctor determines that the potential benefit justifies the potential risk to the unborn baby. Since phenoxymethylpenicillin appears in breast milk, you should consult with your doctor if you plan to breast feed your baby. If this medication is essential to your health, your doctor may advise you to discontinue breast feeding until your treatment is finished.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Phenoxymethylpenicillin Tablets have not been shown to have any effect on ability to drive and use machines.

Phenoxymethylpenicillin Tablets contains potassium

Each Phenoxymethylpenicillin 250mg tablet contains 28mg of potassium. This potassium content may be harmful to people on low potassium diets or reduced kidney function.

3. How to take phenoxymethylpenicillin tablets

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

Each dose should be swallowed with a drink of water, at least 30 minutes before food. Try to space the doses as early as possible throughout the day.

The recommended dose is:

Adults including the elderly and children over 12 years

The usual dosage is 250 milligrams or 500 milligrams (one to two tablets) every 6 hours. This may vary depending on the type of infection you have. If you have poor kidney function the dose may be lowered.

To prevent recurring rheumatic fever

The usual dosage is 250 milligrams (one tablet) daily on a continuing basis.

To prevent pneumococcal infection (e.g. in asplenia and in sickle cell disease)

For adults and children over 12 years, the usual dosage is 500 mg (two tablets) every 12 hours.

Children (under 12)

For children aged between 6 and 12 years of age the usual dosage is 250 milligrams (one tablets) every 6 hours.

6 to 12 years of age: 250mg every 6 hours

1 to 5 years of age: 125mg every 6 hours
Infants (up to 1 year): 62.5mg every 6 hours

Long-term treatment: Up to 6 years of age: 125mg twice daily
6 to 12 years of age: 250mg twice daily

The liquid form of this medicine may be more suitable for children under 6 years of age and those with difficulty in swallowing.

To prevent pneumococcal infection (e.g. in asplenia and in sickle cell disease)
The usual dosage is 250 mg (one tablet) every 12 hours.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed by your doctor.
- Dosage might be changed by your doctor if you have liver problems along with kidney problem.

If you take more Phenoxyethylpenicillin Tablets than you should

Always take your medicine as recommended by your doctor.
Never take more than the recommended dose each day. If you or someone else swallows several of these tablets all together or if you think a child has swallowed any of the tablets, contact your doctor, pharmacist or hospital emergency department immediately. Always take any tablet left over with you and also the box, as this will allow easier identification of the tablets.

Symptoms of overdose may include:
Diarrhoea, nausea, vomiting and rarely seizures (fits) may occur.

If you forget to take Phenoxyethylpenicillin Tablets

If you miss a dose, just carry on with the next one as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenoxyethylpenicillin Tablets

Continue taking Phenoxyethylpenicillin Tablets for the full time of treatment, even if you begin to feel better after a few days. Failure to take a full course of therapy may prevent complete elimination of the infection and infection may start up again.

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

4. Possible side effects

Like all medicines, Penicillin VK Tablets can cause side effects although not everybody gets them. If they occur, they are likely to be temporary and not serious. However, some may be serious and need medical attention.

STOP taking your medicine and tell your doctor immediately or go to your nearest accident and emergency department if you notice any of the following:

- an allergic reaction (symptoms include shortness of breath, skin rash or itching, hives, skin eruptions, swelling of your lips, face or tongue, chills or fever or painful joints, dizziness, allergic reactions may also cause effects to the blood and kidneys).
- pseudomembranous colitis (severe bloody diarrhoea) unusual bleeding or bruising seizures
- peeling/blistering of the skin
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema)

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Upset stomach
- black hairy tongue
- Vomiting or nausea (a feeling of sickness).
- Inflammation of the tongue or mouth.
- Redness of the skin, often itchy, similar to the rash of measles,
- Thrush (a yeast infection of the vagina, mouth or skin folds)
- Jaundice (yellow colouring of the skin and whites of the eyes)
- Hepatitis
- Changes in white blood cell count, reduction in red blood cell count, reduction in blood platelets, which increases risk of bleeding or bruising.
- anaemia (lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- Fits or convulsion (usually following high doses or if you suffer from severe kidney damage)
- Numbness or tingling of the hands and feet.
- Soft stools.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet tell your doctor or pharmacist.

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 (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 Phenoxyethylpenicillin

Keep out of the sight and reach of children.

Do not store above 25° C. Store in the original packaging.

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

Do not use phenoxyethylpenicillin film-coated tablets if you notice any visible signs of deteriorations such as colour change of the tablet from white to off-white or yellowish or if patches appear on the tablet.

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

6. Contents of the pack and other information

What Phenoxymethylpenicillin contains

The active substance is Phenoxymethylpenicillin. Each tablet contains 250 mg of Phenoxymethylpenicillin (as Phenoxymethylpenicillin Potassium).

The other ingredients are:

Calcium Hydrogen Phosphate Dihydrate
Maize Starch
Cellulose, Microcrystalline (E460)
Magnesium Stearate (E572)

Film Coat

Basic Butylated Methacrylate
Macrogol 6000
Sodium Laurylsulfate (E487)
Stearic acid (E570)
Titanium Dioxide (E171)

What Phenoxymethylpenicillin Tablets look like and contents of the pack

Phenoxymethylpenicillin Tablets White, circular, biconvex film-coated tablets with break line on one side and 'I 04' on the other.

Blisters (aluminium – PVC) of 14 tablets. Packs containing 14, 28, 42, 56, 70, 140 tablets are available.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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This leaflet was last approved in 09/2024