

PACKAGE LEAFLET: INFORMATION FOR THE USER



BROWN & BURK

**Phenoxymethylpenicillin Sugar Free
125mg / 5ml Powder for Oral Solution
Phenoxymethylpenicillin Sugar Free
250mg / 5ml Powder for Oral Solution
(Phenoxymethylpenicillin)**

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Phenoxymethylpenicillin is and what it is used for
2. Before you take Phenoxymethylpenicillin Sugar Free Oral Solution
3. How to take Phenoxymethylpenicillin Sugar Free Oral Solution
4. Possible side effects
5. How to store Phenoxymethylpenicillin Sugar Free Oral Solution
6. Further information

1. WHAT PHENOXYMETHYLPENICILLIN IS AND WHAT IT IS USED FOR

The name of your medicine is Phenoxymethylpenicillin which is more commonly called Penicillin V or Penicillin VK.

Phenoxymethylpenicillin is an antibiotic (antibacterial medicine) for treating infections. It belongs to a group of antibiotics called 'penicillins', which work by killing the bacteria that cause infections. Phenoxymethylpenicillin can also be used to prevent infections.

Phenoxymethylpenicillin Sugar Free Oral Solution is used to 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 and prevention of infection in patients without a spleen or patients with sickle cell disease.

2. BEFORE YOU TAKE PHENOXYMETHYLPENICILLIN SUGAR FREE ORAL SOLUTION

DONOT take Phenoxymethylpenicillin

- If you are allergic (hypersensitive) to phenoxymethylpenicillin or to any of the ingredients in this medicine
- if you know that you are allergic to penicillin

Take special care with Phenoxymethylpenicillin if:

- You are pregnant, trying to become pregnant or breast-feeding
- You have ever had a bad reaction to or are allergic to phenoxymethylpenicillin, any other penicillin or cephalosporin or to any other drug
- You suffer from any long-term infection
- You are suffering from any stomach or intestinal problems, such as persistent diarrhoea or vomiting
- You have problems with your kidneys or liver
- You suffer any blood disorders
- You suffer from bronchial asthma or a tendency to develop allergic conditions

You should note that if you test your urine for glucose using a non-enzymatic test phenoxymethylpenicillin 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.

Taking other medicines

Phenoxymethylpenicillin may occasionally interfere with other medicines so it is important that you take care about all the medicines you are taking including those that you have bought without a prescription. In particular, if you are taking any of the following:

- any other antibiotics, for example, erythromycin, neomycin or tetracycline
- probenecid (used to treat gout)
- medicines used to treat cancer, psoriasis, rheumatoid arthritis e.g. methotrexate
- medicine used to treat high blood pressure, water retention or heart conditions e.g. beta blockers, amiloride or spiro lactone
- medicine used to prevent clotting of the blood e.g. warfarin
- medicine used to treat diabetes e.g. guar gum

If you are taking oral contraceptives (the Pill) and have diarrhoea or breakthrough bleeding ('spotting' between periods) this could cause contraceptive failure.

Taking Phenoxymethylpenicillin with food and drink
This medicine should be taken at least 30 minutes before food and preferably not less than two hours after food.

Pregnancy and breast-feeding

The effects of phenoxymethylpenicillin in pregnancy have not been adequately studied. If you are pregnant or planning on becoming pregnant, you should inform your doctor immediately. Phenoxymethylpenicillin should only be used in pregnancy if your doctor decides that the potential benefit to you outweighs the potential risk to the baby.

Since phenoxymethylpenicillin appears in breast milk, you should ask your doctor or pharmacist for advice if you plan to breastfeed.

Driving and using machines

This medicine should not affect your ability to drive or to use machinery.

Important information about some of the ingredients of Phenoxymethylpenicillin

This medicine contains 1/3 mmol potassium per 125mg. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PHENOXYMETHYLPENICILLIN SUGAR FREE ORAL SOLUTION

Always take Phenoxymethylpenicillin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For oral use only.

This medicine should be taken at least 30 minutes before food and preferably not less than two hours after food.

Adults and children (over 12):

The usual dosage is 250 mg to 500 mg every six hours. This may vary depending on the condition being treated.

If you have poor kidney function the dose may be lowered.

Children (under 12):

For children aged between 1 and 5 years of age, the usual dose is 125 mg every six hours.

For children aged between 6 and 12 years of age, the usual dose is 250 mg every six hours.

For preventing the recurrence of rheumatic fever or chorea:
The usual dosage is 250 mg twice daily on a continuing basis.

For the prevention of infection in patients without a spleen or patients with sickle cell disease:

For adults and children over 12 years, the dosage is 500mg every 12 hours.

For children aged between 6 and 12 years, the dosage is 250mg every 12 hours and for children below 5 years, the dosage is 125mg every 12 hours.

For children over 12 years the dose should not exceed the maximum adult doses.

For elderly, the dosage is as for adult. The dosage should be lowered in poor renal function.

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 Phenoxymethylpenicillin than you should

If you (or someone else) swallow a lot of the medicine all at once, or if you think a child has accidentally swallowed any of the medicine, contact your nearest hospital casualty department or your doctor immediately. Always take any remaining medicine with you.

Symptoms of overdose may include diarrhoea, nausea, vomiting and stomach pain.

If you forget to take Phenoxymethylpenicillin

If you forget to take a dose take one as soon as you remember unless it is nearly time to take the next dose. Never take two doses together. Take the remaining doses at the correct time.

If you stop taking Phenoxymethylpenicillin

You should continue to take this medicine for as long as your doctor tells you to. Take the full course. Even if you start to feel better the original infection may still be present and may recur if treatment is stopped.

If you have any further questions regarding the use of this medicine, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If you experience any of the following side effects, stop taking this medicine and tell your doctor IMMEDIATELY:

- An allergic reaction – symptoms such as shortness of breath, skin rash or itching, hives, swelling of your lips, face or tongue, chills or fever or painful joints.
- Unusual bleeding or bruising
- Seizures

Other unwanted effects which may occur are:

- Diarrhoea – should the diarrhoea be persistent or severe stop taking your medicine and tell your doctor IMMEDIATELY
- Nausea (feeling sick), vomiting (being sick) or stomach upset
- Redness of the skin, often itchy, similar to the rash of measles
- Thrush or inflammation of the vaginal area
- Changes in white blood cell count, reduction in red blood cell count, reduction in blood platelets increasing the risk of bleeding or bruising
- Fever
- Painful joints
- Inflammation of the tongue or mouth.

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

5. HOW TO STORE PHENOXYMETHYLPENICILLIN SUGAR FREE ORAL SOLUTION

Keep out of the reach and sight of children.

This medicine after reconstitution should be stored in a refrigerator between 2°C to 8°C in the container supplied and should be used within 7 days of being dispensed by your pharmacist. Do not transfer it to another container. Shake well before use. Keep it in a secure place where children cannot get at it. Do not use this medicine after the expiry date shown on the outside packaging.

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 to protect the environment.

6. FURTHER INFORMATION

What Phenoxymethylpenicillin contains

Phenoxymethylpenicillin Sugar Free Oral Solution contains either 125 mg or 250 mg of phenoxymethylpenicillin in every 5ml.

- The active substance is Phenoxymethylpenicillin (as phenoxymethylpenicillin potassium).
- The other ingredients are Sorbitol (E420), Powdardrome Strawberry Premium (Nature identical flavouring and natural flavouring, maize maltodextrin, INS1520 polypropylene glycol) and Sodium Saccharin.

What Phenoxymethylpenicillin looks like and contents of the pack

Phenoxymethylpenicillin is a white to off-white fine powder for oral solution, which, when reconstituted as directed, yields a colourless to pale yellow solution.

The product is available in a 150 ml HDPE bottle with a child resistant cap. Each bottle contains 100 ml of reconstituted solution with a dosing syringe of 5ml.

Marketing Authorisation Holder and Manufacturer

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