

PACKAGE LEAFLET: INFORMATION FOR THE USER

PHENOXYMETHYLPENICILLIN 125mg/5ml ORAL SOLUTION SUGAR FREE

PHENOXYMETHYLPENICILLIN 250mg/5ml ORAL SOLUTION SUGAR FREE

(Phenoxymethylpenicillin Potassium)

Read this entire 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.
- 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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

Phenoxymethylpenicillin Oral Solution Sugar Free is available in two strengths as a powder for reconstitution. The powder for reconstitution is prepared by the pharmacist before dispensing by adding water to the powder to give 100ml of oral solution. The strength you are given will be decided by your doctor.

Phenoxymethylpenicillin, the active ingredient, is an antibiotic, which belongs to a group of medicines called penicillins, which are used to kill bacteria that cause infections in your body

Your medicine is used to:

- treat bacterial infections of the ear, throat, respiratory tract, skin and soft tissues
- prevent infections such as rheumatic fever or chorea recurring

- prevent pneumococcal infection (e.g. in asplenia and in patients with sickle cell disease).

2. What you need to know before you take this medicine

Do not take this medicine if you:

- You have ever had a bad reaction or allergic reaction to any penicillin-type antibiotic including cephalosporin drugs
- You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic
- You are allergic to any of the ingredients contained in this medicine

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have any medical conditions, and especially if you:

- suffer from kidney problems
- suffer from any stomach problems, e.g. vomiting
- have a history of allergy or asthma

Other medicines and Phenoxymethylpenicillin oral solution

Your medicine may interfere with other medicines that you may be taking. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines even those not prescribed, including herbal and homeopathic remedies.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

- Some other antibiotics (tetracyclines, erythromycin, neomycin and chloramphenicol have been reported to reduce the effect of penicillin)
- Sulfinpyrazone or probenecid (used to treat gout - painful inflammation of the joints)
- methotrexate (a drug used to treat cancer and psoriasis -a chronic skin disease)
- anti-coagulants (medication used to prevent blood clots e.g. warfarin)
- Oral typhoid vaccine (penicillin can stop this from working)

Phenoxymethylpenicillin Solution with food and drink

- Guar gum (used as a thickening agent and normally found in puddings and ice-cream and benefiber) can reduce the absorption of phenoxymethylpenicillin.

Pregnancy, 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.

Driving and using machines

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

Important information about sorbitol and benzoate salt in this medicine:

- This medicine contains sorbitol. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- Sodium benzoate: benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). This medicine contains 20 mg sodium benzoate in each 5ml which is equivalent to 4mg/ml.
- Sunset yellow may cause allergic reactions.

Information on Sodium content:

- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

3. How to take this medicine

- Always take this medicine exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- The dosage and duration of treatment will depend on the type and severity of the infection.
- It should be given in divided doses (4 times a day)
- Take this medicine when your stomach is empty. This means at least 30mins before food and preferably not less than two hours after food.

The following dosage schedule applies to Phenoxy-methylpenicillin Oral Solution Sugar Free:

Adults, elderly and children over 12 years: 250mg-500mg every six hours (one to two 5ml spoonfuls of 250mg/5ml)

Infants (up to 1 year): 62.5 mg every six hours.

Children 1-5 years: 125 mg every six hours (one 5ml spoonful of 125mg/5ml)

6-12 years: 250mg every six hours (one 5ml spoonful of 250mg/5ml or two 5ml spoonfuls of 125mg/5ml)

For preventing the recurrence of rheumatic fever or chorea:

The usual dose is 250mg 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 the 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 Oral Solution Sugar Free than you should

If you accidentally take too many doses, tell your doctor immediately or contact your nearest Hospital casualty/accident and Emergency Department even if there are no signs of discomfort. Take your medicine in its original packaging with you in order to enable the doctor to identify your medicine easily.

If you forget to take Phenoxymethylpenicillin Oral Solution Sugar Free

If you forget to take a dose, take it as soon as you remember, however, if it is almost time for your next dose, skip the missed dose and then take your next dose when it is due.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE.**If you stop taking this medicine**

Take this medicine that has been prescribed for you, even if you start to feel better. If you stop taking the medicine, your condition may re-occur or get worse.

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

4. Possible side effects

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

STOP TAKING this medicine and tell your doctor immediately if you suffer from any of the following:

- an allergic reaction - symptoms may include: shortness of breath, skin rash or itching, hives, swelling of the skin (especially of the lips, face or tongue), chills or fever, painful joints
- severe peeling/blistering of the skin
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema)
- seizures
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever

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

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea
- sore mouth
- hepatitis
- convulsions
- black hairy tongue
- pins and needles or numbness
- sore throats, infections, or fever (may be caused by low white blood cells)
- problems with blood clotting (unusual bleeding or bruising)
- anaemia (may cause lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- jaundice – yellowing of skin or whites of the eyes
- teeth may appear stained, usually returning to normal with brushing (this has been reported in children).

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, you should contact 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 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 this medicine

- Keep this medicine out of the sight and reach of children
- *Unconstituted powder*: Do not store above 25°C. Store in a dry place. *Reconstituted oral solution*: Store for 7 days in a refrigerator
- Do not use this medicine after the expiry date which is stated on the carton (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 Phenoxymethylpenicillin Oral Solution Sugar Free Contains**

- Phenoxymethylpenicillin Oral Solution Sugar Free comes in two strengths 125mg/5ml and 250mg/5ml.
- Each 5ml of reconstituted oral solution contains either 125mg or 250mg of phenoxymethylpenicillin potassium as the active ingredient.
- The other ingredients are sodium benzoate, sorbitol (E420), saccharin sodium, orange flavour sweet permaseal, sunset yellow FCF (E110), colloidal silicon dioxide.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, HP4 1EG, United Kingdom

Telephone: 0044 (0) 1442 200922

Fax: 0044 (0) 1442 873717

Email: info@bristol-labs.co.uk

Phenoxymethylpenicillin 125mg/5ml Oral Solution Sugar Free; PL 17907/0248

Phenoxymethylpenicillin 250mg/5ml Oral Solution Sugar Free; PL 17907/0249

This leaflet was last revised in July 2021

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax, email) above.