



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

P3521T

PHENOXYMETHYLPENICILLIN

125mg/5ml and 250mg/5ml Granules for Oral Solution Sugar Free

Phenoxymethylpenicillin Potassium

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, 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

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2. What you need to know before you take Phenoxymethylpenicillin Oral Solution
3. How to take Phenoxymethylpenicillin Oral Solution
4. Possible side effects
5. How to store Phenoxymethylpenicillin Oral Solution
6. Contents of the pack and other information

1. What Phenoxymethylpenicillin Oral Solution is and what it is used for

This medicine belongs to the penicillin group of antibiotics. Phenoxymethylpenicillin is an antibacterial drug used in the treatment of mild to moderately severe infections such as chest and throat infections, skin and soft tissue infections, infections of the mouth, gums and teeth, scarlet fever (characterised by high fever, sore throat and skin rashes), and mild erysipelas (disease marked by red skin eruptions, chills and fever). Also used in the prevention of rheumatic fever and chorea (a group of disorders characterised by brief rapid involuntary movements of limbs, face, trunk and head).

2. What you need to know before you take Phenoxymethylpenicillin Oral Solution**Do not take Phenoxymethylpenicillin Oral Solution if:**

- you have a history of bad reaction or allergic reactions to any penicillins, cephalosporins or other allergy causing agents
- have ever had a skin rash or swelling of the face or neck or shortness of breath after taking any antibiotic
- you are allergic to phenoxymethylpenicillin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions**Talk to your doctor or pharmacist before taking Phenoxymethylpenicillin Oral Solution if:**

- you are suffering from severe illness, nausea, vomiting, stomach bloating/cramping or difficulty swallowing- your doctor may decide that an oral antibiotic is not of benefit to you
- you suffer from allergies and/or asthma
- you have impaired kidney function or kidney problems, as you may be given a lower dose than normal.
- suffer from allergic reactions to penicillin, cephalosporins or other drugs
- have an intolerance to some sugars, as this medicine contains sorbitol
- if you are taking the contraceptive pill. You may need to take extra contraceptive precaution such as using a condom.

Potentially life-threatening skin rashes (Stevens Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of some penicillin's appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). If you develop a rash or these skin symptoms, stop taking Phenoxymethylpenicillin Oral Solution, seek urgent advice from a doctor and tell them that you are taking this medicine. Prolonged use of an antibiotic may result in infections due to bacteria resistance to the antibiotic.

Other medicines and Phenoxymethylpenicillin Oral Solution

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

- antibacterial medicines e.g. tetracycline, erythromycin, neomycin, chloramphenicol-they have been reported to reduce the effect of penicillin
- probenecid or sulfapyrazone - used for treatment of gout
- guar gum – used in diabetes
- anticoagulants e.g. warfarin (to prevent blood clots)

- methotrexate (to treat cancer or psoriasis)
- oral typhoid vaccine.
- The contraceptive pill (you will need to take extra contraceptive precautions such as using a condom).

Laboratory tests

In patients undergoing long-term treatment with phenoxymethylpenicillin, blood counts and also liver and kidney function should be monitored.

Tell your doctor if you are having urine tests for diabetes or certain liver function tests, as the medicine can affect the results of some tests.

Taking this medicine 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.

This medicine may be present in breast milk and can cause an allergic reaction in the infant. You should not take Phenoxymethylpenicillin Oral Solution if you are breast-feeding.

Driving and using machines

It is not known if Phenoxymethylpenicillin Oral Solution has an effect on your ability to drive and use machines however some of the side effects may affect your ability to drive and use machines.

Phenoxymethylpenicillin Oral Solution contains sorbitol (E420) and sodium

This medicine contains sorbitol. The 125mg/5ml oral solution contains 789.0mg sorbitol in each 5ml dose and 250mg/5ml oral solution contains 654.5mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. 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. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

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

3. How to take Phenoxymethylpenicillin Oral Solution

For oral use. Shake the bottle well before use. Take the medicine half an hour before or at least 3 hours after a meal. The dose will be different for different medical conditions and patients.

Always take 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:

Adults (including the elderly): 125 – 500mg every 4 - 6 hours.

For long-term preventative treatment of rheumatic fever, the dose is 125mg twice a day. The dose will be reduced if you have kidney problems.

Children up to 1 year of age: 62.5mg every 6 hours (the 250mg/5ml strength is not suitable for use).

Children 1 to 5 years of age: 125mg every 6 hours.

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

In patients with bacterial infection (such as streptococcal infection), treatment is continued at the full dosage for 10 days to minimise complications.

If you take more Phenoxymethylpenicillin Oral Solution than you should

Contact your doctor straight away or go to the nearest hospital casualty department. Take with you any remaining oral solution and the container so that the medicine can be identified.

Product:	Phenoxymethylpenicillin 125mg/5ml & 250mg/5ml Granules for Oral Solution Sugar Free
Item Code:	P3521T
Size:	210 x 420mm
Min. Point size:	10pt
O. Artwork	15/08/25
Proof No.	2
Amendment Date	18/08/25
Pharmacode:	1478

Colours Used	
	Process Black
	Keyline - does not print

If you forget to take Phenoxymethylpenicillin

Oral Solution

Take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue with the regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenoxymethylpenicillin

Oral Solution

It is important to finish your prescribed course of this medicine. If you stop taking your medicine too soon, your infection may come back or may get worse.

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.

Hypersensitivity/Allergic reactions of all intensity levels - to the point of anaphylactic shock have also been observed after oral penicillin use. Severe anaphylactoid reactions, which occur significantly less often after oral administration of penicillin than after intravenous or intramuscular administration, may require appropriate emergency management.

If you develop any of the reactions listed below – IMMEDIATELY STOP taking your medicine and contact your doctor or go to the nearest hospital.

- swelling of the throat and severe allergic reaction/hypersensitivity (symptoms are itchy, red or swollen skin, wheeziness, shortness of breath (bronchospasm)/difficulty in breathing, changes in blood counts, swelling of the face, lips, cheeks, eyelids or tongue and in severe cases collapse), muscle weakness, laryngeal oedema (accumulation of fluid in the larynx), increase in the heartbeat, vasculitis (inflammation of blood vessels) and a sudden drop in blood pressure up to life threatening shock
- allergic skin reaction include- skin eruptions including nettle rash/hives (urticaria), itching or rarely severe blistering/peeling of the skin
- serum sickness (symptoms are feeling of coldness, fever, swelling of the body, joint pains, extreme exhaustion)
- convulsions (fits)
- severe diarrhoea usually with blood or mucus, stomach pain and fever.
- pseudomembranous enterocolitis (bacterial infection of the large intestine. Symptoms include abdominal pain and diarrhoea)

Tell your doctor or pharmacist if you notice any of the side effects in the following sections:

Very Common: (May affect more than 1 in 10 people)

- loss of appetite

Common: may affect up to 1 in 10 people

- nausea (feeling sick), vomiting (getting sick), stomach ache/ pain, diarrhoea and cramps.
- pain or discomfort in the upper abdomen (gastric discomfort)
- gas (flatulence)
- inflamed and sore mouth (stomatitis), inflammation of the tongue (glossitis)
- rash, itchy skin, hives (immediate presence of hives indicates penicillin allergy, use of Phenoxymethylpenicillin should be discontinued)
- eruption of the skin (exanthema)

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

- Sore throat
- Black hairy tongue (discolouration of tongue)

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

- blistering and/or peeling of the skin, severe inflammation of the entire skin surface (shedding of the top layers of your skin (Exfoliative dermatitis)), Toxic epidermal necrolysis (which causes severe illness and flaking of the skin)
- dry mouth and changes in taste
- change in liver test results
- blood pressure decreased
- allergic vasculitis (*sudden blue colouring of the skin, painful joints, kidney inflammation, mild fever*)
- growth of bacteria or yeast on the tongue

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

- a change in the number of white or red blood cells and platelets (symptoms can be bleeding under the skin and easier bruising, pale yellow skin, weakness or breathlessness, or make infections more likely)
- lower-than-normal levels of white blood cells (more bruises than normal, or worse than normal, small red dots under skin, unusually bleeding (gums/nose), blood in urine/stools)
- higher than normal level of white blood cells (eosinophilia)
- yellowing of the skin or whites of the eyes, pale stools and dark urine (all symptoms of cholestatic jaundice),

loss of appetite, stomach discomfort caused by liver or blood problems

- inflammation of the kidney which can cause swollen ankles or high blood pressure.
- Hepatitis
- sore throats, infections or fever/chills, faster heart rate (may be caused by low levels of white blood cells)
- coagulation disorders (problems with blood clotting (easy bruising or prolonged bleeding))
- haemolytic anaemia (lack of energy or tiredness, cold hands/feet, pale skin)
- severe skin reactions such as Stevens-Johnson syndrome
- serum sickness-like reactions (characterised by fever, chills, arthralgia and oedema)
- tooth discolourations
- severe, watery diarrhoea, along with pus/mucus in stool, severe cramps/abdominal tenderness, nausea (pseudomembranous enterocolitis)

Not known: frequency cannot be estimated from the available data

- problems with blood clotting
- tingling or numbness/ pins and needles (paraesthesia)
- kidney disease
- central nervous system toxicity (symptoms including but not limited to anxiety, dizziness, numbness, light-headedness, and tinnitus)

You may develop a yeast/fungal infection if you have been taking this medicine for a long period.

If you notice any of the above side effects or notice any other side effects and think your medicine may be causing them 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 Phenoxymethylpenicillin Oral Solution

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 pack. The expiry date refers to the last day of that month.

Dry granules: Do not store above 25°C. Keep the bottle tightly closed.

Oral Solution: Store in a refrigerator (2 - 8°C). Keep the bottle tightly closed. Use within 7 days of preparation.

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 contains

This medicine is available in 2 strengths.

Each 5ml of oral solution contains 125mg or 250mg of phenoxymethylpenicillin (as potassium salt) as the active ingredient. The other ingredients are sorbitol (E420), saccharin sodium and strawberry flavour containing flavourings, maltodextrin, gum acacia, propylene glycol (E1520), triacetin & ascorbic acid.

What Phenoxymethylpenicillin Oral Solution looks like and contents of the pack

Phenoxymethylpenicillin Oral Solution is a clear, colourless solution with an odour of strawberry. Prior to reconstitution with water the product is white to off white powder with an odour of strawberry.

This medicine is available in a pack size of 100 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Crescent Pharma Limited,
Units 3 & 4, Quidhampton Business Units,
Polhampton Lane, Overton, Hants, RG25 3ED, UK.

Manufacturer:

Crescent Manufacturing Ltd,
2 Cunard Road, Park Royal,
London, NW10 6PN, UK

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If you would like this leaflet in a different format please contact the licence holder at the above address.

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