

PACKAGE LEAFLET

Package Leaflet: Information for the user

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 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 Phenoxymethylpenicillin Sugar Free Oral Solution is and what it is used for
2. What you need to know 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. Contents of the pack and other information

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

Phenoxymethylpenicillin Sugar Free Oral Solution is available in two strengths as a powder for reconstitution. 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 Phenoxymethylpenicillin Sugar Free Oral Solution

Do not take Phenoxymethylpenicillin Sugar Free Oral Solution if:

- You are allergic to Phenoxymethylpenicillin or any of the other ingredients of this medicine (listed in section 6).
- 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

Warnings and precautions

Talk to your doctor or pharmacist before taking Phenoxymethylpenicillin Sugar Free Oral Solution if:

- You suffer from any stomach problems, e.g. vomiting

- You suffer from any kidney problems
- You suffer from allergies and/or asthma.

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.

Other medicines and Phenoxymethylpenicillin Sugar Free Oral Solution:

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

Talk to your doctor or pharmacist if you are taking:

- Methotrexate (a drug used to treat cancers and psoriasis)
- Some other antibiotics (tetracyclines, erythromycin, neomycin and chloramphenicol have been reported to reduce the effect of penicillin)
- Sulfinpyrazone or probenecid (medicines used to treat gout)
- Anti-coagulants (e.g. warfarin - to prevent blood clots)
- Oral typhoid vaccine (penicillin can stop this from working)

Phenoxymethylpenicillin Sugar Free Oral 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 and breast-feeding

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 some of the ingredients in your medicine

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.

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.

3. How to take Phenoxymethylpenicillin Sugar Free Oral Solution

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 dose will depend on the patient and will be decided by your doctor.
The usual doses for each age group are as follows:

Adults including the elderly and children over 12 years

250 mg to 500 mg every six hours (5 ml to 10 ml of 250 mg/5ml)

Children

Infants (up to 1 year): 62.5 mg every 6 hours

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

6-12 years: 250mg every six hours (5 ml of 250 mg/5 ml or 10 ml of 125 mg/5ml)

For preventing the recurrence of rheumatic fever or chorea:

The usual dose 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.

When to take your medicine

Phenoxymethylpenicillin Sugar Free Oral Solution is usually prescribed to be taken four times a day. It is best to take it as evenly spaced as possible.

Take this medicine when your stomach is empty. This means at least 30mins before food and preferably not less than two hours after food.

If you take more Phenoxymethylpenicillin Sugar Free Oral Solution than you should

If you accidentally take too much medicine, contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Phenoxymethylpenicillin Sugar Free Oral Solution

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you 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 the medicine and tell your doctor IMMEDIATELY if you experience 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 (frequency common)
- severe peeling/blistering of the skin (frequency rare)

- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema) (frequency not known)
- Seizures (frequency not known)
- profuse watery diarrhoea usually with blood and mucus, stomach pain and fever (frequency not known)

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

Common side effects (may affect up to 1 in 10 people)

- stomach pain or cramps, nausea (feeling sick), vomiting (being sick) and diarrhoea

Uncommon side effects (may affect up to 1 to 100 people):

- kidney problems, which might cause blood in the urine or reduced amounts of urine

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

- Hepatitis
- sore throats, infections, or fever (may be caused by low white blood cells)
- anaemia (may cause lack of energy or tiredness)
- jaundice - yellowing of skin or whites of the eyes

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

- sore mouth
- black hairy tongue
- problems with blood clotting (unusual bleeding or bruising)
- Pins and needles or numbness

If any of the side effects gets serious, or if you notice any side effects 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Ireland HPRa Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phenoxymethylpenicillin Sugar Free Oral Solution

Keep out of the sight and reach 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.

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 Sugar Free Oral Solution contains

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

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

Brown & Burk IR Limited
22 Northumberland Road,
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Manufacturer

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This leaflet was last revised on 03/2021