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 antibiotic or other 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, accompanied by vomiting or diarrhoea - your doctor may decide that an oral antibiotic is not of benefit to you
- You suffer from any kidney problems, as you may be given a lower dose than normal
- You suffer from allergies and/or asthma.
- You suffer from allergic reactions to penicillin, cephalosporins or other drugs
- 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 Powder for 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 Sugar Free 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.

Talk to your doctor or pharmacist if you are taking:

- Methotrexate (a drug used to treat cancers and psoriasis)
- Some other antibiotics (tetracyclines, 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)
- 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.

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.

You should not take Phenoxymethylpenicillin Sugar Free Powder for Oral Suspension if you are breast-feeding.

Driving and using machines

This medicine should not affect your ability to drive or to use machinery however some of the side effects may affect your ability to drive and use machines.

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.

For 125mg / 5ml

This medicine contains 955.55 mg sorbitol in each 5 mL dose, which is equivalent to 191.11 mg/mL

For 250mg / 5ml

This medicine contains 814.15 mg sorbitol in each 5 mL dose, which is equivalent to 162.83 mg/mL

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 unit in each 5 ml dose, that is essentially to say 'sodium-free'

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 (one to two 5 ml to spoonful's of 250 mg/5ml every six hours)

Children
Infants (up to 1 year): 62.5 mg every 6 hours **(a half 5 ml spoonful of 125/5ml every six hours)**
1- 5 years: 125mg every six hours (one 5 ml spoonful of 125 mg/5ml every six hours)
6-12 years: 250mg every six hours (one 5 ml spoonful of 250 mg/5 ml or two 5ml spoonful's of 125 mg/5ml every six hours)

For preventing the recurrence of rheumatic fever or chorea:
The usual dose is 250 mg twice daily (one 5ml spoonful of 250mg/5ml 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.
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 your medicine on an empty stomach either half an hour before a meal or at least three hours after a meal.

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.

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.

STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following:

- Hypersensitivity of all severities (allergic reaction) (frequency – very rare)
  - Symptoms may include: difficulty breathing, muscle weakness, fever, joint pain, changes in blood counts, sudden swelling of the lips, cheeks, eyelids, tongue and throat, laryngeal oedema (accumulation of fluid in the larynx), bronchospasm (wheezing, shortness of breath), increase in the heartbeat, vasculitis (inflammation of blood vessels) and a sudden drop in blood pressure up to life threatening shock
- A serious skin reaction characterized by reddish non-elevated target like or circular patches on the trunk, often cetral blisters or mucosal lesions, skin peeling, ulcers of mouth, throat, genitals and eyes. These serious skin rashes can be preceded by fever and flu like symptoms (Toxic epidermal necrosis (frequnecy – not known)/Stevens –Johnsons syndrome (frequency – very rare)).
- allergic reactions including rash, itching, hives and rarely severe peeling/blistering of the skin (frequency - common)
- Serum sickness-like reactions (characterised by fever, chills, joint pains and oedema) (frequency – very rare)

- Seizures (frequency not known)
- 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 following and they worry you.

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

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

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

- sore mouth
- black hairy tongue (discolouration of tongue)

Rare side effects (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))
- dry mouth
- changes in taste
- change in liver test results
- blood pressure decreased
- growth of bacteria or yeast on the tongue

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

- yellow colour of the skin and whites of the eyes, pale stools (all symptoms of cholestatic jaundice)
- Hepatitis
- Sore throats, infections, or fever/chills, faster heart rate (may be caused by low white blood cells)
- lower-than-normal levels of white blood cells
- higher than normal level of white blood cells (eosinophilia)
- coagulation disorders (problems with blood clotting (easy bruising or prolonged bleeding))
- haemolytic anaemia (may cause lack of energy or tiredness, cold hands/feet, pale skin)
- lower-than-normal levels of platelets (a type of blood cell) (more bruises than normal, or worse than normal, small red dots under skin, unusually bleeding (gums/nose), blood in urine/stools)
- kidney problems, which might cause blood in the urine or increased amounts of urine (interstitial nephritis)
- tooth discolouration

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

- Pins and needles or numbness (paraesthesia)
- central nervous system toxicity (symptoms including but not limited to anxiety, dizziness, numbness, light-headedness, and tinnitus)

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website: 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 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 and Manufacturer

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