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Heading font size : 9 pt.
Main fonts size : 9 pt.
Line Spacing : 3mm

Phenoxymethylpenicillin 125mg & 250mg
Powder for Oral solution (POM)
Leaflet Size : 148 x 500 mm
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500 mm

148 mm

Front Side

PACKAGE LEAFLET: INFORMATION FOR THE USER

PHENOXYMETHYLPENICILLIN 125MG/5ML AND 250MG/5ML

POWDER FOR ORAL SOLUTION

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 or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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 Powder for Oral Solution is and what it is used for

2. What you need to know before you take Phenoxymethylpenicillin Powder for Oral Solution

3. How to take Phenoxymethylpenicillin Powder for Oral Solution

4. Possible side effects

5. How to store Phenoxymethylpenicillin Powder for Oral Solution

6. Contents of the pack and other information

1. WHAT PHENOXYMETHYL
PENICILLIN POWDER FOR ORAL
SOLUTION IS AND WHAT IT IS
USED FOR

The name of your medicine is Phenoxymethylpenicillin 125mg/5ml and 250mg/5ml Powder for Oral Solution. It 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 (an abnormal involuntary movement disorder) recurring

Phenoxymethylpenicillin is indicated for prevention against:

- Pneumococcal Infection (e.g. in patients without a spleen or patients with sickle cell disease).

2. WHAT YOU NEED TO KNOW
BEFORE YOU TAKE
PHENOXYMETHYLPENICILLIN
POWDER FOR ORAL SOLUTION

Do not take Phenoxymethylpenicillin Powder for Oral Solution if:

- You ever had a bad reaction or allergic reaction to any Phenoxymethylpenicillin or Cephalosporin-type antibiotic. An example of a Cephalosporin-type antibiotic is Cefradine.
- 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 (hypersensitive) to Phenoxymethylpenicillin or any of the other ingredients of this medicine (listed in Section 6)

Warnings and precautions

- You suffer from any stomach problems, e.g. vomiting
- You suffer from any kidney problems
- You suffer from allergies and/or asthma

Other medicines and Phenoxymethylpenicillin Powder for 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.

Talk to your doctor or pharmacist or nurse before taking:

- Methotrexate (a drug used to treat cancers and psoriasis)
- Anticoagulants (e.g. warfarin – to prevent blood clots)
- Sulfinpyrazone or Probenecid (medicines used to treat gout)
- Oral Typhoid vaccine (penicillin can stop this from working)
- Some other antibiotics (Tetracycline, Erythromycin, Chloramphenicol, and Neomycin)

Phenoxymethylpenicillin Powder for Oral Solution with food and drink

Take your medicine on an empty stomach either half an hour before a meal or at least

three hours after a meal. Guar gum can cause reduced absorption of phenoxymethylpenicillin. Your doctor will advise you about this.

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.

Phenoxymethylpenicillin Powder for Oral Solution contains Sucrose and Sodium. Sucrose

Phenoxymethylpenicillin 125mg/5ml Powder for Oral Solution contains 2.31g of sucrose per 5ml dose. Phenoxymethylpenicillin 250mg/5ml Powder for Oral Solution contains 2.17g of sucrose per 5ml dose.

- May be harmful to teeth.
- 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
POWDER FOR ORAL SOLUTION

Follow all directions given to you by your doctor or pharmacist. Their directions may differ from the information contained in this leaflet.

The pharmacist's label should tell you how much to take and how often. If it does not, or you are not sure, check with your doctor or pharmacist.

How much of your medicine to take

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

250mg to 500mg every six hours (one to two 5ml spoonfuls of 250mg/5ml)

250mg twice daily is recommended for long term prevention of rheumatic fever (one 5ml spoonful of 250mg/5ml)

Children

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

1-5 years: 125mg 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 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,

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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

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.

How long to take your medicine for

Keep taking this medicine until your doctor tells you to stop.

Do not stop taking it just because you feel better.

If you take more Phenoxymethylpenicillin Powder for Oral Solution 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 Powder for 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 Phenoxymethylpenicillin Powder for Oral Solution

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
- 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

The following are the more common effects. Tell your doctor or pharmacist if they worry you.

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

The following are other possible side effects:

Mouth

- sore mouth
- black hairy tongue
- sore throats

Skin

- pins and needles or numbness

Blood

- problems with blood clotting (unusual bleeding or bruising)

infections or fever (may be caused by low white blood cells)

anaemia (may cause lack of energy or tiredness)

Kidney

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

Liver

- jaundice – yellowing of skin or whites of the eyes

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
PHENOXYMETHYLPENICILLIN
POWDER FOR 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 label. The expiry date refers to the last day of that month.

Dry powder: Store below 25°C, Store in the original package.

Reconstituted solution: Store up to 7 days at 2°C-8°C in a refrigerator.

If your doctor tells you to stop your treatment return any left over to the pharmacist.

Only keep it if your doctor tells you to.

Do not throw away any medicines via wastewater.

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 Powder for Oral Solution contains:

Active ingredient: Each 5ml of oral solution contains 125mg or 250mg of phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

Other ingredients: Sucrose, Saccharin Sodium (E954), Orange flavour, Refreshing flavour

What Phenoxymethylpenicillin Powder for Oral Solution looks like and contents of the pack

Powder: White to off white granular powder, free from agglomerates or caking.

Reconstituted solution: Slight opaque solution with orange odour.

Phenoxymethylpenicillin 125mg/5ml and 250mg/5ml Powder for Oral Solution are available in the size of 100ml on reconstitution in the Translucent HDPE round bottle with White Round polypropylene CR Cap.

Marketing Authorization Holder

Flamingo Pharma (UK) Ltd.

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