

## **PATIENT INFORMATION LEAFLET**

### **Phenoxymethylpenicillin 125mg/5ml and 250mg/5ml Oral Solution**

**Read all of this leaflet carefully before you start taking this medicine because it contains information for you.**

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, ask your doctor or pharmacist (chemist).**
- **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 Oral Solution is and what it is used for
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**

The name of your medicine is Phenoxymethylpenicillin 125mg/5ml and 250mg/5ml 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 recurring.

Phenoxymethylpenicillin is indicated for prophylaxis against:

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

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PHENOXYMETHYLPENICILLIN ORAL SOLUTION**

**Do not take Phenoxymethylpenicillin 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 are allergic to any of the ingredients contained in this medicine.
- You are taking methotrexate (a cytotoxic drug used to treat cancers and psoriasis)

**Take special care with your medicine if:**

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

**Taking other medicines**

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:

- 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)

**Taking 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 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.

**Phenoxymethylpenicillin Oral Solution contains Sucrose, Potassium, E124 & E110****Sucrose**

Phenoxymethylpenicillin 125mg/5ml Oral Solution contains 2.80g of sucrose per 5ml dose.

Phenoxymethylpenicillin 250mg/5ml Oral Solution contains 2.89g of sucrose per 5ml dose.

- This should be taken into account in patients with diabetes mellitus. 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.

**Potassium**

Phenoxymethylpenicillin 125mg/5ml Oral Solution contains 14.2mg of potassium per 5ml dose.

Phenoxymethylpenicillin 250mg/5ml Oral Solution contains 28.4mg of potassium per 5ml dose.

- This should be taken into account by patients with reduced kidney function or patients on a controlled potassium diet.

**E124 & E110**

Ponceau 4R (E124) and sunset yellow (E110) may cause allergic type reactions.

**3. HOW TO TAKE PHENOXYMETHYLPENICILLIN ORAL SOLUTION**

**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)

Prophylactic use: 250mg twice daily is recommended for long term prophylaxis of rheumatic fever (one 5ml spoonful of 250mg/5ml)

**Children**

**Infants (up to 1 year):** 62.5mg every six 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 125 mg/5ml)

**When to take your medicine**

Phenoxymethylpenicillin should be given in divided doses (4 times a day) or as directed by your doctor. Take your medicine on an empty stomach either half an hour before a meal or at least three hours after a meal.

**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 Oral Solution than you should**

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

**If you forget to take Phenoxymethylpenicillin Oral Solution**

If you do forget to take a dose of Phenoxymethylpenicillin Oral Solution at the correct time, take it as soon as you remember, then carry on as before.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking your medicine**

If you stop taking the medicine before your doctor tells you to stop, 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 or nurse.

**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
- 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 diarrhoea

**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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE PHENOXYMETHYLPENICILLIN ORAL SOLUTION**

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

**Expiry Date**

Do not use your medicine after the expiry date stated on the label. The expiry date refers to the last day of the month.

**Storage Conditions**

Store in the original package. Keep the bottle tightly closed.

Dry powder: Store in a dry place below 25°C. Protect from light.

Reconstituted solution: Store up to 7 days in a refrigerator.

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.

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.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Phenoxymethylpenicillin Oral Solution contains**

Each 5ml spoonful of oral solution contains 125mg or 250mg of phenoxymethylpenicillin as phenoxymethylpenicillin potassium. It also contains sodium benzoate, saccharin sodium, trusil orange flavour, orange colour (containing sunset yellow (E110) and ponceau 4R (E124)) and sucrose.

### **What Phenoxymethylpenicillin Oral Solution looks like and contents of the pack**

Dry powder: an off white pale pink granular powder.

Reconstituted solution: a clear orange solution with an orange odour and flavour.

Phenoxymethylpenicillin Oral Solution is available in size 100ml on reconstitution.

### **The product licence holder and manufacturer is:**

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

### **Your medicine is distributed by:**

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, UK

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