

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

<p style="text-align: center;"><b>Kopen Sugar Free 125mg/5ml and 250mg/5ml Powder for Oral Solution Phenoxymethylpenicillin</b></p>
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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 further questions, please 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 of the 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 **Kopen Sugar Free Powder for Oral Solution** is and what it is used for
- 2) What you need to know before you take **Kopen Sugar Free Powder for Oral Solution**
- 3) How to take **Kopen Sugar Free Powder for Oral Solution**
- 4) Possible side-effects
- 5) How to store **Kopen Sugar Free Powder for Oral Solution**
- 6) Contents of the pack and other information

#### **1. What Kopen Sugar Free Powder for Oral Solution is and what it is used for**

The name of your medicine is Kopen Sugar Free Powder for Oral Solution. It is available as an off white 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 reconstituted oral solution appears as a clear orange solution with an orange odour and flavour.

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:
  - infection occurring in patients without a spleen or in patients with sickle cell disease (a blood disorder)
  - rheumatic fever.

#### **2. What you need to know before you take Kopen Sugar Free Powder for Oral Solution**

**Do not take Kopen Sugar Free Powder for Oral Solution if you:**

- are allergic to Phenoxymethylpenicillin, or any of the other ingredients of this medicine listed in section 6
- have ever had a bad reaction or allergic reaction to any penicillin-type antibiotic, cephalosporin antibiotic or other drugs
- have ever had a skin rash or swelling of the face or neck or shortness of breath after taking any antibiotic

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Kopen Sugar Free Powder for Oral Solution if you:

- suffer from any kidney problems, as you may be given a lower dose than normal
- suffer from stomach problems accompanied by vomiting or diarrhoea – your doctor may decide that an oral antibiotic is not of benefit to you
- you suffer from allergies and/or asthma
- suffer from allergic reactions to penicillin, cephalosporins or other drugs
- have an intolerance to some sugars, as this medicine contains sorbitol

### **Other medicines and Kopen Sugar Free 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, including herbal and homeopathic remedies.

Inform your doctor if you are taking:

- certain other antibiotics, for example, tetracycline, erythromycin, neomycin or chloramphenicol – they have been reported to reduce the effect of penicillin
- probenecid (medicines used to treat gout)
- methotrexate (a drug used to treat cancers and psoriasis)

### **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 and breast-feeding**

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

It is not known if Kopen Sugar Free Powder for 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.

### **Kopen Sugar Free Powder for Oral Solution contains:**

- **Ponceau 4R (E124) and sunset yellow (E110):** Can cause allergic reactions.
- **Sorbitol:** 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 Kopen Sugar Free 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. The dose will depend on the patient and will be decided 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.

The usual doses for each age group are:

**Adults, including the elderly:**

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

**Children:**

- **Infants (up to 1 year):** 62.5mg every six hours (**a half 5ml spoonful of 125mg/5ml every six hours**)
- 1- 5 years: 125mg every six hours (one 5ml spoonful of 125mg/5ml every six hours)
- 6 - 12 years: 250mg every six hours (one 5ml spoonful of 250mg/5ml or two 5ml spoonfuls of 125mg/5ml every six hours)
- Over 12 years: Same as adult dose

***For prevention of infection in patients without a spleen or patients with sickle cell disease:***

Adults 500mg every 12 hours

Children 6 – 12 years 250mg every 12 hours

Children <5 years 125mg every 12 hours

***To prevent recurrence of rheumatic fever:***

250mg twice daily (one 5ml spoonful of 250mg/5ml twice daily)

**If you take more Kopen Sugar Free Powder For Oral Solution than you should:**

If you accidentally take too much Kopen Sugar Free Powder For Oral Solution, contact your doctor or pharmacist who will recommend what action you should take.

**If you forget to take Kopen Sugar Free 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 the dose you have missed.

**If you stop taking your 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.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects although not everybody gets them.

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

- hypersensitivity- symptoms may include: shortness of breath, sudden blue colouring of the skin, dizziness, swelling of lips, face or tongue, chills or fever, generalised swelling, painful joints
- allergic reactions including skin rashes, itching and hives and rarely, severe blistering/peeling of the skin
- watery or bloody diarrhoea

**The following are the more common effects. Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- stomach ache, flatulence, nausea (feeling sick), vomiting (getting sick), cramps and diarrhoea, rash, itchy skin.

***Very common side effects include:***

- Loss of appetite

***Uncommon side effects include:***

- sore mouth
- black hairy tongue

***Rare side effects include:***

- peeling of the skin
- dry mouth and changes in taste (following Phenoxymethylpenicillin use)
- serum sickness-like reactions (characterised by fever, chills, arthralgia and oedema)
- severe diarrhoea
- change in liver test results
- If you develop thrush, you may need to get treatment from your doctor/pharmacist.

***Very Rare side effects include:***

- jaundice (yellow colour of the skin and whites of the eyes)
- hepatitis
- sore throats, infections or fever (may be caused by low white blood cells)
- problems with blood clotting (easy bruising or prolonged bleeding)
- anaemia (lack of energy or tiredness)
- kidney problems, which might cause blood in the urine or reduced amounts of urine
- blood pressure decreased

***Side effects with unknown frequency include***

- pins and needles or numbness
- convulsions, especially with high doses or in patients with severe kidney problems

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail:

[medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Kopen Sugar Free Powder for Oral Solution**

**KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.**

### **Expiry Date**

Do not use your medicine after the expiry date which is stated on the label. The expiry date, listed as “expiry” on the label, refers to the last day of that month.

### **Storage Conditions**

Kopen Sugar Free Powder for Oral Solution should be stored as follows:

Dry powder: Store below 25°C. Store bottle in the original carton. Keep the bottle tightly closed in order to protect from moisture.

Reconstituted solution: Store for 7 days at 2°C-8°C in a refrigerator. Store in the original container. Keep the container tightly closed. Discard after 7 days.

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 Kopen Sugar Free Powder for Oral Solution contains**

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

Other ingredients: sodium benzoate (E211), saccharin sodium, trusil orange flavour, orange colour (containing sunset yellow (E110), and ponceau 4R (E124)), sorbitol (E420) and ammonium glycyrrhizate.

### **What Kopen Sugar Free Powder for Oral Solution looks like and contents of the pack**

The unreconstituted powder is an off-white, granular powder.

The reconstituted oral solution is a clear orange solution with an orange odour and flavour.

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

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

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This leaflet was last revised September 2015