

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

<p style="text-align: center;">Kopen Sugar Free 125mg/5ml and 250mg/5ml Powder for Oral Solution Phenoxymethylpenicillin</p>

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.
- 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
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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 a pale yellow 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 yellow 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
- 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
- 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 Kopen Sugar Free 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 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.

Please consult 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)
- 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.

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.

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

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.

Important information about some of the ingredients in your medicine

Kopen Sugar Free Powder for Oral Solution contains sorbitol, sodium and sodium benzoate.

The 125mg/5ml solution contains 792.93 mg of sorbitol in each 5 ml dose.

The 250mg/5ml solution contains 800.00 mg of sorbitol in each 5 ml dose.

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'.

This medicine contains 16 mg sodium benzoate in each 5ml dose. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to four weeks old).

3. How to take Kopen Sugar Free Powder for Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. 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 Kopen Sugar Free Powder For Oral Solution

Keep taking Kopen Sugar Free Powder For Oral Solution 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.

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

- hypersensitivity of all severities (allergic reaction)
 - 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
- allergic skin reactions including rash, itching, hives and rarely, severe blistering/peeling of the skin
- pseudomembranous enterocolitis (bacterial infection of the large intestine. Symptoms include abdominal pain and diarrhoea)

Very common: (may affect more than 1 in 10 people)

- loss of appetite

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

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

Uncommon: (may affect up to 1 in 100 people)

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

Rare: (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)), Toxic epidermal necrolysis (which causes severe illness and flaking of the skin)
- dry mouth and changes in taste
- change in liver test results
- blood pressure decreased
- allergic vasculitis (*sudden blue colouring of the skin, painful joints, kidney inflammation, mild fever*)
- growth of bacteria or yeast on the tongue

Very rare: (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 levels of 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 (anaemia (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)
- severe skin reactions such as Stevens-Johnson syndrome
- serum sickness-like reactions (characterised by fever, chills, arthralgia and oedema)
- tooth discolouration
- severe, watery diarrhoea, along with pus/mucus in stool, severe cramps/abdominal tenderness, nausea (pseudomembranous enterocolitis)

Not known: (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRC Pharmacovigilance, Website: www.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, quinoline yellow (E104), sorbitol (E420) and ammonium glycyrrhizate.

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

The unreconstituted powder is a pale yellow, granular powder.

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

A 5 ml graduated measuring spoon is supplied with this product.

Marketing Authorisation Holder:

Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

Manufacturer:

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

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