

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Kopen 250mg Tablets 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 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 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 250mg Tablets are and what they are used for
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1. What Kopen 250mg Tablets are and what they are used for

The name of your medicine is Kopen 250mg Tablets. These tablets are dispensed by the pharmacist.

Kopen 250mg Tablets contains Phenoxyethylpenicillin, which is a penicillin antibiotic, used to kill bacteria that cause infections in your body.

Kopen 250mg Tablets are 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 250mg Tablets

Do not take Kopen 250mg Tablets if you:

- are allergic to Phenoxyethylpenicillin, 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 antibiotics including ampicillin or cephalosporin antibiotics
- 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 Kopen 250mg Tablets if you:

- suffer from any kidney problems, as a lower dose may be prescribed
- suffer from allergies and/or asthma
- suffer from stomach problems accompanied by vomiting or diarrhoea – an oral antibiotic may not be of benefit to you
- suffer from allergic reactions to penicillin, cephalosporins or other drugs.

Other medicines and Kopen 250mg Tablets

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 (medicine 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 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 breastfeeding, 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

No effects are known.

Important information about some of the ingredients in your medicine

Each tablet contains lactose monohydrate. 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 250mg Tablets

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

The dose will depend on the patient and will be decided by your doctor. However, the usual dose for each age group is:

Adults (including the Elderly):

250mg to 500mg every six hours

Children:

Infants (up to 1 year): Tablets are not usually given to this age group. Other form(s) of this medicine may be more suitable for children, ask your doctor or pharmacist.

1 - 5 years: 125mg every six hours

6 - 12 years: 250mg every six hours

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

250mg twice daily is recommended to prevent recurrence of rheumatic fever.

When to take your medicine

Kopen 250mg Tablets are usually prescribed to be taken either three or 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 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.

If you take more Kopen 250mg Tablets 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 Kopen 250mg Tablets

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.

4. Possible side effects

Like all medicines phenoxymethylpenicillin 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:

- hypersensitivity – symptoms may include: shortness of breath, sudden blue colouring of the skin, dizziness, swelling of lips, face or tongue, chills or fever, sweating, painful joints, nausea, vomiting, rash, faster heartbeat, shock.
- 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 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

Common side effects include:

- Inflammation of the mouth, tongue or lips

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 colouring 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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517 Website: www.hpra.ie, E-mail:

medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE KOPEN 250MG TABLETS

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

Expiry Date

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

Storage Conditions

Kopen 250mg Tablets should be stored at a temperature below 25°C. Store in the original container to protect from moisture.

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. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Kopen 250mg Tablets contain:

Active ingredient: Each tablet contains 250mg of phenoxymethylpenicillin (as phenoxymethylpenicillin potassium).

Other ingredients: lactose monohydrate, magnesium stearate, talc and maize starch.

What Kopen 250mg Tablets looks like and contents of the pack

Kopen 250mg Tablets are circular and white, approximately 10.5mm in diameter and embossed with "Pen 250". These tablets are available in packs of 100/500/1000. Not all pack sizes may be marketed.

The product licence holder and manufacturer is:

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

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