NEW ZEALAND CONSUMER MEDICINE INFORMATION



ALPHAMOX

Amoxicillin 250 mg and 500 mg capsules

What is in this leaflet

Please read this leaflet carefully before you start taking Alphamox.

This leaflet answers some common questions about Alphamox.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Alphamox against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Alphamox is used for

Alphamox contains the active ingredient amoxicillin, which is an antibiotic that belongs to a group of medicines called penicillins. These medicines work by killing the bacteria that are causing the infection.

Alphamox is used to treat infections in different parts of the body caused by bacteria.

Alphamox can also be used to prevent endocarditis (heart infection) in some people.

Alphamox will not work against infections caused by viruses, such as colds or flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Alphamox for another reason.

Alphamox is available only with a doctor's prescription.

Before you take Alphamox

When you must not take it.

Do not take Alphamox if you have an allergy to:

- any medicine containing amoxicillin
- penicillin or any other similar antibiotics such as cephalosporins or other beta-lactam medicines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you have had an allergic reaction (such as a rash) when taking an antibiotic, you should tell your doctor before you take Alphamox.

Do not take Alphamox after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- glandular fever
- leukaemia
- history of seizures
- an allergic reaction (such as a rash) to any antibiotic in the past.

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Alphamox.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Alphamox may interfere with each other. These include:

- anticoagulants (used to thin the blood) such as acenocoumarol or warfarin.
- probenecid and allopurinol, medicines used to treat gout.
- the oral contraceptive pill (birth control pill).
 Talk to your doctor about the need for additional contraception while taking

Alphamox. Like other antibiotics, Alphamox may reduce the effectiveness of some birth control pills.

- methotrexate, a medicine used to treat some cancers, psoriasis and arthritis.
- · other antibiotics.

These medicines may be affected by Alphamox or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Alphamox

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

Your doctor will tell you how much you need to take each day and when to take it. This depends on your condition and whether or not you are taking any other medicines.

For the treatment of most infections, the usual adult dose is 250 to 500 mg every 8 hours.

For children, the dose may vary depending on the child's weight.

People with kidney problems may need smaller doses.

For the prevention of endocarditis (heart infection) in people undergoing dental procedures, Alphamox is usually taken one hour

prior to the procedure. Your doctor or dentist will advise you.

How to take it

Swallow the capsules whole with a glass of water.

Alphamox can be taken with or without food.

If taking high doses of amoxicillin, make sure that adequate fluid is taken so kidney output is not reduced.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely, or your symptoms may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Alphamox

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Alphamox.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Tell your doctor if you become pregnant while taking this medicine.

If you are about to have any diagnostic tests, tell your doctor that you are taking Alphamox. It may interfere with results when testing for the presence of glucose in urine, or when testing for oestriol levels in pregnancy.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to check your kidneys, liver and blood are working

normally.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking Alphamox. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping Alphamox, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of Alphamox allows fungi to

grow and the above symptoms to occur. Alphamox does not work against fungi.

Things you must not do

Do not take Alphamox to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage, even if you feel better after a few days, unless advised by your doctor. If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

Things to be careful of

Be careful driving or operating machinery until you know how Alphamox affects you.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Alphamox.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- upset stomach (feeling sick, being sick or diarrhoea)
- crystals in the urine, which may be seen as cloudy urine
- problems urinating
- convulsions (fits or seizures).

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking

Alphamox.

Alphamox treats infections in most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting, indigestion
- diarrhoea (several loose bowel movements per day)
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)
- hyperkinesia (spasm)
- dizziness and convulsions
- anaemia (tiredness)
- discoloured teeth.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- any type of skin rash, itching, blistering or peeling of the skin, hives
- swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing
- wheezing, shortness of breath or difficulty breathing
- fever, chills, headache, fast heart rate, fast breathing rate, flushing, muscle pain and anxiety (these symptoms may be a reaction to toxins released by bacteria when destroyed by this medicine)

- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- · fits or seizures
- watery and severe diarrhoea, which may also be bloody
- sever stomach cramps
- yellowing of the skin and eyes
- decreased amount of urine or dark coloured urine or pale stools
- difficulty or pain on passing
 urine
- headache, fever and stiff neck (these are symptoms of aseptic meningitis)
- prolonged vomiting (mainly seen in children taking amoxicillin) without allergic skin reactions of difficulty breathing but may have abdominal pain and diarrhoea. In severe cases this may lead to shock.
- hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in a heart attack.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects even after treatment with Alphamox.

Hypersensitivity reactions are more likely to occur in people with a history of penicillin hypersensitivity and in people who have eczema.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Alphamox

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Alphamox or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Alphamox where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Alphamox capsules come in two strengths:

- Alphamox 250 mg
- Alphamox 500 mg

Alphamox 250 mg and 500 mg capsules are hard gelatin capsules with an ivory body and green cap. The capsules are filled with an almost white granular powder.

Ingredients

Active ingredient:

Alphamox 250 capsule contains 250 mg of amoxicillin as the active ingredient.

Alphamox 500 capsule contains 500 mg of amoxicillin as the active ingredient.

Inactive ingredients:

Alphamox capsule shells also contain:

- purified talc
- sodium starch glycollate
- magnesium stearate
- gelatin
- iron oxide yellow
- titanium dioxide
- brilliant blue
- microcrystalline cellulose
 [250 mg capsules only]
- colloidal anhydrous silica [500 mg capsules only].

Contains sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Alphamox is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie Auckland

www.viatris.co.nz Telephone: 0800 168 169

Date of Information

04 December 2023 (Based on Alphamox datasheet dated 04 December 2023).