NEW ZEALAND CONSUMER MEDICINE INFORMATION

ALPHAMOX 125 AND 250

Amoxicillin 125 mg/5mL and 250 mg/5mL Oral powder for suspension

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 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.

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.

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 or any other penicillin
- beta-lactam antibiotics including cephalosporin antibiotics
- 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.

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
- phenylketonuria.

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 warfarin
- probenecid and allopurinol, medicines used to treat gout
- tetracycline medicines (used to treat some infections) such as doxycycline and minocycline
- methotrexate, a medicine used to treat some forms of cancer

• 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.

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

Shake the bottle vigorously for 15 seconds before measuring the correct dose using a suitable measuring device. Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

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.

Alphamox can be taken with or without 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 and pharmacist that you are taking Alphamox.

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

Tell your doctor if you become pregnant while 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any diagnostic tests, tell your doctor that you are taking Alphamox. It may interfere with the results of some tests.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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.

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 make sure the medicine is working and to prevent unwanted side effects.

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.

This medicine may cause (allergic reactions, dizziness, convulsion) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your 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 nausea, vomiting and diarrhoea.

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.

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
- diarrhoea
- headache
- discoloured teeth

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

Tell your doctor as soon as possible if you notice any of the following:

- mild skin rash, hives or itchy skin
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)
- increase in muscle movement
- dark tongue that looks furry

The above list includes serious side effects that may require medical attention. Serious side effects are rare

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

- a severe, painful, red or purple rash with blistering or peeling of the skin, which can develop after fever and flu like symptoms and may also include bleeding in lips, eves, mouth and nose
- red rash distributed symmetrically that commonly appears on the buttocks or in skin folds
- swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing

- wheezing, shortness of breath or difficulty breathing
- 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
- severe stomach cramps
- yellowing of the skin and eyes
- decreased amount of urine
 or dark coloured urine
- fever, nausea, vomiting and headache with a stiff neck and extreme sensitivity to bring light
- 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. These side effects may only develop a few weeks after you have stopped taking Alphamox. 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.

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

After taking Alphamox

Storage

Keep Alphamox suspension in the refrigerator (2-8°C) but not in the freezer. Do not use any suspension left in the bottle after 14 days.

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 suspension come in two strengths:

- Alphamox 125 mg/5mL
- Alphamox 250 mg/5mL

Both suspensions are white to cream coloured, raspberry flavoured and sugar free. Each bottle contains 100 mL of suspension.

Ingredients

<u>Active ingredient(s):</u> Each 5 mL of Alphamox 125 suspension contains 125 mg of the active ingredient amoxicillin.

Each 5 mL of Alphamox 250 suspension contains 250 mg of the active ingredient amoxicillin.

Inactive ingredient(s): The suspensions also contains

- Propylene glycol alginate
- Sodium benzoate
- Aspartame
- Sodium citrate dihydrate
- Disodium edetate
- Colloidal anhydrous silica
- Sorbitol
- Maltodextrin
- Propylene glycol

- Starch
- Natural flavouring

Contains aspartame, benzoates and sorbitol.

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 <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

12 August 2024 (Based on Alphamox datasheet dated 12 August 2024).