

ALPHAMOX

amoxicillin (as trihydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ALPHAMOX. It does not contain all of 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, talk to 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.

ALPHAMOX is used to treat a range of infections caused by bacteria.

These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

ALPHAMOX works by killing the bacteria that causes these infections. 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 it for another reason.

This medicine is available only with a doctor's prescription.

Before you take ALPHAMOX

When you must not take it

Do not take ALPHAMOX if you are allergic to:

- any medicine containing amoxicillin
- penicillin or any other similar antibiotics such as cephalosporins
- 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 this medicine 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, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

ALPHAMOX may be used in pregnancy. It has been used in a large number of pregnant women without any proven increase in harmful effects on the developing baby. However, your doctor will discuss with you the risks and benefits of taking ALPHAMOX during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

ALPHAMOX passes into breast milk. Your doctor will discuss the risks and benefits of taking ALPHAMOX when breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- kidney or liver problems. The dosage of ALPHAMOX may need to be changed or you may need to be given an alternative medicine
- leukaemia
- glandular fever (mononucleosis) or a blood disorder

Tell your doctor if you plan to have surgery.

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 may be affected by ALPHAMOX, or may affect how well it works. These include:

- probenecid and allopurinol, medicines used to treat gout
- certain other antibiotics, such as tetracyclines
- anticoagulants such as warfarin, which is used to prevent blood clots.
- the contraceptive pill (birth control pill)

Talk to your doctor about the need for additional contraception while taking ALPHAMOX.

ALPHAMOX, like other antibiotics, may reduce the effectiveness of some birth control pills.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

If you have not told your doctor about any of the above, tell them before you start taking ALPHAMOX.

How to take ALPHAMOX

Follow all directions given to you by your doctor and 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

Take ALPHAMOX as directed by your doctor or pharmacist.

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 ALPHAMOX

ALPHAMOX can be taken with or without food.

Capsules: swallow whole with a glass of water.

Mixture: shake the bottle well before measuring the correct dose using a suitable medicine measure.

How long to take it

Continue taking ALPHAMOX until you finish the capsules or mixture, or for as long as your doctor tells you.

Do not stop taking ALPHAMOX even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

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 you missed.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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.

While you are taking ALPHAMOX

Things you must do

If you are about to be started on any new medicine, remind 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 your symptoms do not improve within a few days, or if they become worse, tell your doctor.

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 such as Lomotil or Imodium without checking with your doctor.

Things you must not do

Do not use ALPHAMOX to treat any other conditions unless your doctor tells you to.

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

Side effects

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

This medicine helps most people with treating infections, 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 treatment if you get some of the side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

While you are taking it

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

- nausea (feeling sick), vomiting
- diarrhoea
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)

The above list includes the milder side effects of your medicine.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- watery or severe diarrhoea (several loose bowel movements per day), which may also be bloody
- indigestion
- severe stomach cramps
- bleeding or bruising more easily than normal
- mouth ulcers

- yellowing of the skin and eyes
- dark coloured urine or pale stools
- difficulty or pain on passing urine; decreased amount of urine

The above list includes serious side effects which may require medical attention.

If any of the following allergic reactions happen, stop taking ALPHAMOX and tell your doctor immediately, or go to Accident and Emergency at the 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

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

After you have finished taking it

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with ALPHAMOX:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- fever, in combination with one or both of the above

These are rare but serious side effects. You may need urgent medical attention. Do not take any diarrhoea medicine without checking with your doctor.

Tell your doctor if you notice anything that is making you feel unwell.

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

After using ALPHAMOX

Storage

Keep ALPHAMOX in the packaging until it is time to take it.

If you take the medicine out of the packaging they may not keep well.

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

Keep ALPHAMOX mixture in the refrigerator but not in the freezer. Do not use any mixture 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 in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep ALPHAMOX where children cannot reach it.

A locked cupboard at least one-and-a-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 is available as capsules or mixtures.

CAPSULES

ALPHAMOX capsules are available in 2 strengths:

- ALPHAMOX 250
- ALPHAMOX 500

For both strengths, the capsules are green and cream in colour.

Each pack contains 20 capsules.

MIXTURES

ALPHAMOX mixtures are available in 2 strengths:

- ALPHAMOX 125
- ALPHAMOX 250

Both mixtures are white to cream coloured, raspberry flavoured and sugar free.

Each bottle contains 100 mL of mixture.

Ingredients

The active ingredient in ALPHAMOX capsules and mixtures is amoxicillin (as amoxicillin trihydrate).

CAPSULES

Each ALPHAMOX 250 capsule contains 250 mg of the active ingredient amoxicillin.

Each ALPHAMOX 500 capsule contains 500 mg of the active ingredient amoxicillin.

The capsules also contain the following inactive ingredients:

- purified talc
- sodium starch glycollate
- magnesium stearate
- microcrystalline cellulose [ALPHAMOX 250 only]
- colloidal anhydrous silica
- sodium lauryl sulfate
- gelatin
- iron oxide yellow CI77492 (172)
- titanium dioxide (171)
- brilliant blue FCF CI42090 (133).

The capsules are gluten free.

MIXTURES

Each 5 mL of ALPHAMOX 125 mixture contains 125 mg of the active ingredient amoxicillin.

Each 5 mL of ALPHAMOX 250 mixture contains 250 mg of the active ingredient amoxicillin.

The mixtures also contain the following inactive ingredients:

- sorbitol
- propylene glycol alginate

- aspartame (951)
- disodium edetate
- sodium citrate
- colloidal anhydrous silica
- sodium benzoate (211)
- Raspberry Flavour Permaseal 10458-31.

The mixtures are sugar free and gluten free.

Supplier

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

CAPSULES

ALPHAMOX 250 - AUST R 17656 & 17678

ALPHAMOX 500 - AUST R 17657 & 17679

MIXTURES

ALPHAMOX 125 - AUST R 54149

ALPHAMOX 250 - AUST R 54150

This leaflet was prepared in November 2017.

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