ALPHAMOX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking ALPHAMOX?

ALPHAMOX contains the active ingredient amoxicillin (as trihydrate). ALPHAMOX is used to treat a range of infections caused by bacteria.

For more information, see Section 1. Why am I taking ALPHAMOX? in the full CMI.

2. What should I know before I take ALPHAMOX?

Do not take if you have ever had an allergic reaction to amoxicillin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take ALPHAMOX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALPHAMOX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take ALPHAMOX?

- The usual adult dose of ALPHAMOX is one dose three times a day e.g. every 8 hours.
- Swallow ALPHAMOX 250 mg and 500 mg capsules whole with a glass of water. It can be taken with or without food.
- Keep taking ALPHAMOX until the course is finished or for as long as your doctor tells you.

More instructions can be found in Section 4. How do I take ALPHAMOX? in the full CMI.

5. What should I know while taking ALPHAMOX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ALPHAMOX.

	• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. • Tell your doctor immediately if you develop severe itching or swelling, a skin rash, or severe diarrhoea, even if they occur several weeks after stopping ALPHAMOX. • If your symptoms do not improve within a few days, or if they become worse, tell your doctor.
Things you should not do	• Do not give ALPHAMOX to anyone else, even if they have the same condition as you. • Do not take ALPHAMOX to treat any other complaints unless your doctor says to.
Driving or using machines	• Be careful driving or operating machinery until you know how ALPHAMOX affects you.

Looking after your medicine	• Keep your capsules in the blister pack until it is time to take them. • Keep it in a cool dry place, away from moisture or heat, where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking ALPHAMOX? in the full CMI.

6. Are there any side effects?

Less serious side effects: nausea, vomiting, diarrhoea, oral thrush (white, furry sore tongue and mouth) and vaginal thrush (sore and itchy vagina, vaginal discharge). **Serious side effects:** unusual bleeding or bruising more easily than normal; mouth ulcers; yellowing of the skin or eyes; dark urine or pale stools; difficulty or pain on passing urine; watery or severe diarrhoea; excessive abnormal muscle movements; dizziness or convulsions; or a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, or neck; an allergic reaction (rash, itching, blistering or peeling of skin, wheezing, swelling of the face/lips/mouth/throat, difficulty in breathing or swallowing, lumpy rash (hives), or fainting). Serious side effects that can occur several weeks after stopping ALPHAMOX are watery and severe diarrhoea (may be bloody), severe stomach cramps and fever with these symptoms. For more information, including what to do if you have any

side effects, see Section 6. Are there any side effects? in the full CMI.

ALPHAMOX®

Active ingredient(s): *amoxicillin (as trihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALPHAMOX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALPHAMOX.**

Where to find information in this leaflet:

1. Why am I taking ALPHAMOX?
2. What should I know before I take ALPHAMOX?
3. What if I am taking other medicines?
4. How do I take ALPHAMOX?
5. What should I know while taking ALPHAMOX?
6. Are there any side effects?
7. Product details

1. Why am I taking ALPHAMOX?

ALPHAMOX contains the active ingredient amoxicillin (as trihydrate). ALPHAMOX belongs to a group of antibiotic 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 cause these infections. ALPHAMOX can also be used to prevent infections including 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 ALPHAMOX has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

There is no evidence that ALPHAMOX is addictive.

2. What should I know before I take ALPHAMOX?

Warnings

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 any other parts of the body
  - rash, itching or hives on the skin.

  If you have ever had an allergic reaction (such as a rash) when taking an antibiotic, you should tell your doctor before you take ALPHAMOX.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

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

Check with your doctor if you:

- have any other medical conditions, especially the following:
  - glandular fever (mononucleosis)
  - leukaemia
  - blood disorders
  - kidney or liver problems

  (Your dose may need to be changed or you may need to be given an alternate medicine)
- take any medicines for any other condition.
- have ever had an allergic reaction (such as a rash) to any antibiotics in the past.

- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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

ALPHAMOX may be taken during 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 the risks, and benefits of taking ALPHAMOX during pregnancy.

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

ALPHAMOX can pass to your baby from breast milk. Your doctor will discuss the risks and benefits of taking ALPHAMOX when breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription

from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ALPHAMOX and affect how it works. These include:

- medicines used to treat gout e.g. probenecid or allopurinol
- contraceptive pill (birth control pill)
- certain other antibiotics such as tetracyclines
- anticoagulants (used to prevent blood clots) such as warfarin
- methotrexate, a medicine used to treat arthritis and some types of cancers

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALPHAMOX.

ALPHAMOX may influence the results of some laboratory tests.

4. How do I take ALPHAMOX?

How much to take

Take ALPHAMOX as directed by your doctor or pharmacist.

The dosage of ALPHAMOX 250 mg & 500 mg capsules varies widely and depends on the patient, the condition being treated and the response to the treatment.

For the treatment of most infections, the usual adult dose is 250 to 500 mg three times a day e.g. 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.

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

How to take ALPHAMOX

Swallow whole with a glass of water.

ALPHAMOX can be taken with or without food.

How long to take ALPHAMOX for

Keep taking ALPHAMOX until the course is finished or for as long as your doctor tells you.

Do not stop taking ALPHAMOX just because you feel better as the infection may return.

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

Do not change the dose without first checking with your doctor.

If you forget to take ALPHAMOX

If you miss your dose at the usual time, take it as soon as you remember. Then go back to taking it as directed by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

Do not take two doses within an hour or so of each other.

Taking more than the prescribed dose can increase the chance of unwanted side effects.

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 ALPHAMOX

If you think that you or anyone else has taken too much ALPHAMOX, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre **(Australia telephone 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ALPHAMOX?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Tell your doctor or pharmacist you are taking ALPHAMOX before starting any other prescribed medicine.

Some medicines may affect the way other medicines work.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

Call your doctor straight away if you:

- develop itching, swelling or a skin rash when you are taking ALPHAMOX. Do not take any more ALPHAMOX.
- develop severe diarrhoea when taking ALPHAMOX.

  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 medication to stop the diarrhoea (e.g. Lomotil or Imodium) without checking with your doctor.

Remind any doctor, dentist or pharmacist you visit that you are taking ALPHAMOX.

Things you should not do

Do not give ALPHAMOX to anyone else, even if their symptoms seem similar to yours.

Do not take ALPHAMOX to treat any other complaints unless your doctor says to.

Driving or using machines

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

Looking after your medicine

- 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.
- Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• nausea (feeling sick), vomiting • diarrhoea • oral thrush (white, furry sore tongue and mouth) • vaginal thrush (sore and itchy vagina, vaginal discharge)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• unusual bleeding or bruising more easily than normal • yellowing of the skin or eyes • dark urine or pale stools	**Tell your doctor immediately or go to the Emergency Department of your nearest hospital if you experience any of these serious side effects.**

Serious side effects	What to do
• difficulty or pain on passing urine; decreased amount of urine • watery or severe diarrhoea (several loose bowel movements per day), which may also be bloody • indigestion • severe stomach cramps • mouth ulcers • excessive abnormal muscle movements • dizziness or convulsions • a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck	
Signs of allergic reaction: • any type of skin rash, itching, blistering or peeling of the skin, lumpy rash (hives) • swelling of the face, lips, mouth or throat which	**STOP taking ALPHAMOX and contact your doctor immediately or go to the emergency department of your nearest hospital if you experience any of these serious side effects**.

Serious side effects	What to do
may cause difficulty swallowing or breathing • wheezing, shortness of breath or difficulty breathing, fainting	

After you have finished taking ALPHAMOX

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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems . By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ALPHAMOX contains

Active ingredient **(main ingredient)**	Amoxicillin (as trihydrate) 250 mg and 500 mg per capsule
Other ingredients **(inactive ingredients)**	• purified talc • sodium starch glycollate • magnesium stearate • microcrystalline cellulose [ALPHAMOX 250 only] • colloidal anhydrous silica • sodium lauryl sulfate • Empty Hard Gelatin Capsule Shell Cap - Green Opaque Body - Ivory Opaque Size 2 (ID

	12436) [ALPHAMOX 250 only] • Empty Hard Gelatin Capsule Shells Cap - Green Opaque Body - Ivory Opaque Size 0el (ID 12361) [ALPHAMOX 500 only]
Potential allergens	• sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What ALPHAMOX looks like

ALPHAMOX is available in two strengths:

- **ALPHAMOX 250:** hard gelatin capsule with ivory body and green cap Size "2" filled with almost white granular powder (AUST R 17678).
- **ALPHAMOX 500:** hard gelatin capsule of size "0el" having FEA ivory opaque body and FEG green opaque cap filled with white/almost white granular powder (AUST R 17679).

Each pack contains 20 capsules.

Who distributes ALPHAMOX

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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ALPHAMOX® is a Viatris company trade mark

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