

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 using FISAMOX?

FISAMOX contains the active ingredient amoxicillin sodium. FISAMOX is used to treat some infections in different parts of the body caused by bacteria. For more information, see Section [1. Why am I using FISAMOX?](#) in the full CMI.

2. What should I know before I use FISAMOX?

Do not use if you have ever had an allergic reaction to FISAMOX 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 use FISAMOX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FISAMOX 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 use FISAMOX?

FISAMOX must only be given by a doctor or nurse. More instructions can be found in Section [4. How do I use FISAMOX?](#) in the full CMI.

5. What should I know while using FISAMOX?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist who is treating you that you have been given FISAMOX.If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.If you develop itching with swelling or skin rash or difficulty breathing after you have been given FISAMOX, you may be having an allergic reaction to FISAMOX. Contact your doctor immediately.If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after FISAMOX has been stopped.
Things you should not do	<ul style="list-style-type: none">If you experience diarrhoea, do not take any diarrhoea medicine without first checking with your doctor.Do not breast-feed while using this medicine.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how FISAMOX affects you.
Looking after your medicine	<ul style="list-style-type: none">FISAMOX will be stored in the pharmacy or on the ward.FISAMOX is kept in a cool dry place, protected from light and moisture, where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using FISAMOX?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: oral thrush - white, furry, sore tongue and mouth, vaginal thrush - sore and itchy vagina and/or discharge, a mild rash or pain or redness at the site of injection.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following: severe rash or any type of skin rash, itching, blistering or peeling of the skin, hives, red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck, wheezing, irregular heartbeat or you are feeling faint, swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing.

Tell your doctor immediately if you notice any of the following side effects, even if they occur up to several weeks after finishing treatment with FISAMOX: severe abdominal cramps or stomach cramps, watery and severe diarrhoea, which may also be bloody, or fever, in combination with one or both of the aforementioned side effects.

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.

FISAMOX[®]

Active ingredient(s): *amoxicillin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FISAMOX. **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 FISAMOX.**

Where to find information in this leaflet:

- [1. Why am I using FISAMOX?](#)
- [2. What should I know before I use FISAMOX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FISAMOX?](#)
- [5. What should I know while using FISAMOX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FISAMOX?

FISAMOX contains the active ingredient **amoxicillin sodium**. FISAMOX is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

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

FISAMOX will not work against infections caused by viruses, such as colds or the 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.

There is no evidence that FISAMOX is addictive.

2. What should I know before I use FISAMOX?

Warnings

Do not use FISAMOX if:

- you are allergic to any medicine containing amoxicillin or penicillin, any other similar antibiotics such as cephalosporins or 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

Always check the ingredients to make sure you can use this medicine.

Tell your doctor if you have suffered from any allergic conditions due to the use of penicillin.

- you have ever had liver problems as a result of taking penicillins.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- have or have had any of the following medical conditions:
 - asthma
 - kidney or liver disease

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

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

Check with your doctor if you are pregnant or intend to become pregnant.

Do not breast-feed if you are using this medicine.

The active ingredient in FISAMOX passes into breast milk and there is a possibility that your baby may be affected.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 FISAMOX. These include:

- probenecid, a medicine used to treat gout
- allopurinol (these are medicines used to treat gout or kidney stones)
- any other antibiotics such as tetracyclines, erythromycin and chloramphenicol
- anticoagulants such as warfarin, which is used to prevent blood clots
- methotrexate, a medicine used to treat arthritis and some types of cancers.

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

Your doctor has more information on medicines to be careful with or avoid whilst receiving FISAMOX.

Some antibiotics may decrease the effectiveness of some birth control pills.

Talk to your doctor about the need for an additional method of contraception whilst receiving FISAMOX.

4. How do I use FISAMOX?

How FISAMOX is given

FISAMOX may be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle

FISAMOX must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you receive FISAMOX. This depends on your infection and other factors, such as your weight. For most infections, FISAMOX is usually given in divided doses throughout the day.

Sometimes only a single dose of FISAMOX is required for the treatment and prevention of certain infections.

If you are given too much FISAMOX

This rarely happens as FISAMOX is administered under the care of a highly trained doctor or nurse. However, if you are given too much FISAMOX, you may experience some of the effects listed under '[6. Are there any side effects?](#)' below. Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

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 using FISAMOX?

Things you should do

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you get a sore white mouth or tongue after you have been given FISAMOX, tell your doctor. Also tell your doctor if you get a vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of FISAMOX allows fungi to grow and the above symptoms to occur. FISAMOX does not work against fungi.
- If you become pregnant while you are receiving FISAMOX, tell your doctor.

- If you have to have any urine tests tell your doctor you have been given FISAMOX. FISAMOX may affect the results of some tests.

Call your doctor straight away:

- **If you develop itching with swelling or skin rash or difficulty breathing after you have been given FISAMOX, you may be having an allergic reaction to FISAMOX.**
- **If you develop severe diarrhoea. Call your doctor immediately even if it occurs several weeks after FISAMOX has been stopped.**

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 first checking with your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using FISAMOX.

Driving or using machines

Be careful driving or operating machinery until you know how FISAMOX affects you. FISAMOX generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, FISAMOX may cause dizziness, drowsiness or tiredness in some people.

Looking after your medicine

FISAMOX will be stored in the pharmacy or on the ward. FISAMOX is kept in a cool dry place, protected from light and moisture, where the temperature stays below 25°C.

FISAMOX is not to be given after the expiry date on the label.

6. Are there any side effects?

Tell your doctor as soon as possible if you have any problems whilst receiving FISAMOX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

This medicine helps most people with 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 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.

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

Whilst being given FISAMOX

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• oral thrush - white, furry, sore tongue and mouth	Speak to your doctor if you

Less serious side effects	What to do
<ul style="list-style-type: none"> vaginal thrush - sore and itchy vagina and/or discharge a mild rash pain or redness at the site of injection 	<p>have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> a severe rash or 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 irregular heartbeat feeling faint a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

After finishing FISAMOX

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> severe abdominal cramps or stomach cramps watery and severe diarrhoea, which may also be bloody fever, in combination with one or both of the above <p>FISAMOX can change bacteria (which are normally present in the bowel and normally harmless) to multiply and therefore cause the above symptoms.</p> <ul style="list-style-type: none"> an illness consisting of a rash, swollen glands, joint pains and fever may occur about a week after treatment. 	<p>Tell your doctor immediately if you notice any of the following rare but serious side effects, even if they occur up to several weeks after finishing treatment with FISAMOX.</p>

Do not take any diarrhoea medicine without first 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 FISAMOX contains

Active ingredient (main ingredient)	1000 mg of amoxicillin (as amoxicillin sodium)
-------------------------------------	--

Do not take this medicine if you are allergic to this ingredient.

What FISAMOX looks like

FISAMOX is a fine white to off-white homogenous powder which must be dissolved in water before it is injected.

It is available in packs of 10 vials.

(AUST R 90880).

Sponsor

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in December 2024.

FISAMOX® is a Viatris company trade mark

FISAMOX_cmi\Dec24/00