

APO-AMOXICILLIN

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 APO-AMOXICILLIN?

APO-AMOXICILLIN contains a penicillin called amoxicillin (as trihydrate) as the active ingredient.

APO-AMOXICILLIN belongs to the penicillin group of antibiotics.

APO-AMOXICILLIN 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 tissue.

For more information, see Section [1. Why am I taking APO-AMOXICILLIN?](#) in the full CMI.

2. What should I know before I take APO-AMOXICILLIN?

Do not take if you are allergic to penicillin or similar types of antibiotics (such as cephalosporins), or any of the ingredients listed at the end of the CMI. If you have ever had an allergic reaction (such as a rash) when taking an antibiotic, you should tell your doctor before you take APO-AMOXICILLIN.

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 APO-AMOXICILLIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-AMOXICILLIN 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 APO-AMOXICILLIN?

- Follow the directions given to you by your doctor and pharmacist. Their directions may differ from the information contained in this leaflet.

More instructions can be found in Section [4. How do I take APO-AMOXICILLIN?](#) in the full CMI.

5. What should I know while taking APO-AMOXICILLIN?

Things you should do	<ul style="list-style-type: none">• Take APO-AMOXICILLIN exactly as your doctor has prescribed.• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.• Remind any doctor, dentist or pharmacist you visit that you are taking APO-AMOXICILLIN.• Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting APO-AMOXICILLIN.
Things you should not do	<ul style="list-style-type: none">• Do not give APO-AMOXICILLIN to anyone else, even if their symptoms seem similar to yours.• Do not take APO-AMOXICILLIN to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APO-AMOXICILLIN affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the original pack until it is time to take them.• Store it in a cool dry place, away from moisture where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking APO-AMOXICILLIN?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects are diarrhoea, indigestion, feeling sick (nausea), vomiting. White furry, sore tongue and mouth (oral thrush). Soreness or itching of the vagina or vaginal discharge (vaginal thrush). Headache, dizziness, tiredness. Teeth discolouration. Unusually active (hyperactivity).

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.

APO-AMOXYCILLIN

Active ingredient: *amoxicillin (as trihydrate)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking APO-AMOXYCILLIN?

APO-AMOXYCILLIN contains the active ingredient **amoxicillin (as trihydrate)**.

APO-AMOXYCILLIN belongs to the penicillin group of antibiotics.

APO-AMOXYCILLIN is used to treat a range of infections caused by bacteria. These infections may affect the chest (e.g. pneumonia), tonsils (e.g. tonsillitis), sinuses (e.g. sinusitis), urinary and genital tract, skin and fleshy tissues.

APO-AMOXYCILLIN works by killing the bacteria that causes infections. APO-AMOXYCILLIN can also be used to prevent infection.

Your doctor may prescribe APO-AMOXYCILLIN for another use. If you want more information, ask your doctor. There is no evidence that APO-AMOXYCILLIN is addictive.

2. What should I know before I take APO-AMOXYCILLIN?

Warnings

Do not take APO-AMOXYCILLIN if:

- you are allergic to amoxicillin (as trihydrate), penicillin or similar types of 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 skin rash, itching, difficulty in breathing and swelling of the face or tongue.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can take APO-AMOXYCILLIN.

Do not give APO-AMOXYCILLIN to anyone else, your doctor has prescribed it specifically for you and your condition.

Check with your doctor if you:

- have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- are allergic to foods, dyes, preservatives or any other medicines.
- have glandular fever (mononucleosis) or lymphatic leukaemia.
- have any kidney or liver problems.
The dosage of APO-AMOXYCILLIN may need to be changed or you may need to be given an alternative medicine.
- have to test your urine for sugar.
APO-AMOXYCILLIN may affect the results of these tests.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

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

Your doctor will discuss with you the possible risks and benefits of taking APO-AMOXYCILLIN during pregnancy or while you are breastfeeding. APO-AMOXYCILLIN passes to your baby from breast milk.

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.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- acenocoumarol, warfarin or other medicines used to prevent blood clots.
- medicines used to treat gout (e.g. probenecid or allopurinol).
- other antibiotics (e.g. tetracyclines). These may interfere with the actions of APO-AMOXYCILLIN.

- methotrexate (a medicine used to treat cancer or rheumatic diseases).
- contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking APO-AMOXICILLIN.

Some medicines may interfere with APO-AMOXICILLIN and affect how it works. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-AMOXICILLIN.

4. How do I take APO-AMOXICILLIN?

Follow the directions given to you by your doctor and pharmacist. Their directions may differ from the information contained in this leaflet.

Please read the direction label carefully. If you have any concerns about how to take APO-AMOXICILLIN, talk to your doctor or pharmacist.

How much to take

Your doctor will tell you the dose of APO-AMOXICILLIN you will need to take each day. This depends on the condition being treated and whether other medicines are being taken.

When to take it

Space the doses as evenly as possible throughout the day. For example, if you are taking APO-AMOXICILLIN three times a day, take a dose about every eight hours.

How to take it

APO-AMOXICILLIN can be taken with or without food. The effects of APO-AMOXICILLIN are not changed by food.

Swallow APO-AMOXICILLIN capsule whole with a full glass of water.

How long to take it for

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

Do not stop taking APO-AMOXICILLIN just because you feel better as the infection can return.

Do not stop taking APO-AMOXICILLIN, or change the dose, without first checking with your doctor.

If you forget to take APO-AMOXICILLIN

If it is almost time for your next dose, skip the dose you missed and take your next dose at the normal time. Otherwise, take the missed dose as soon as you remember and then go back to taking APO-AMOXICILLIN as directed by your doctor.

Do not take a double dose to make up for the dose you missed. Taking more than the prescribed dose can increase the chance of unwanted side-effects.

If you take too much APO-AMOXICILLIN

If you think that you have taken too much APO-AMOXICILLIN, you may need urgent medical attention.

You should immediately:

- drink plenty of water
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Symptoms of overdose include mild to severe nausea, vomiting, cramps and diarrhoea.

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

5. What should I know while taking APO-AMOXICILLIN?

Things you should do

- Take APO-AMOXICILLIN exactly as your doctor has prescribed.
- Tell your doctor if, for any reason, you have not taken APO-AMOXICILLIN exactly as directed. Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.
- Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting APO-AMOXICILLIN.
- Tell your doctor if you develop itching, swelling or a skin rash when taking APO-AMOXICILLIN, do not take any more APO-AMOXICILLIN and tell your doctor immediately.
- Tell your doctor if you develop severe diarrhoea either when taking APO-AMOXICILLIN or within several weeks after treatment, tell your doctor immediately. Diarrhoea may mean 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®).
- Tell your doctor if you get a sore white mouth or tongue while taking or soon after stopping APO-AMOXICILLIN.
- Tell your doctor if you have vaginal itching or discharge. This may mean you have a fungal infection called vaginal thrush. Sometimes taking APO-AMOXICILLIN allows fungi to grow and the above symptoms occur.
- If you have to test your urine for sugar while you are taking APO-AMOXICILLIN, ensure your doctor knows which type of test you use. APO-AMOXICILLIN may affect the results of some of these tests.
- Remind any doctor, dentist or pharmacist you visit that you are taking APO-AMOXICILLIN before starting any

other medicines. Some medicines may affect the way other medicines work.

Things you should not do

- **Do not stop taking APO-AMOXICILLIN because you are feeling better, unless advised by your doctor.** If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.
- Do not give APO-AMOXICILLIN to anyone else, even if their symptoms seem similar to yours.
- Do not take APO-AMOXICILLIN to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-AMOXICILLIN affects you.

Generally, this medicine does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, APO-AMOXICILLIN may cause dizziness or tiredness in some people.

Looking after your medicine

Keep your capsules in the original pack until it is time to take them. If you take the capsules out of its original pack it may not keep well.

Store in a cool dry place, away from moisture where the temperature stays below 25°C. Do not store it:

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not take APO-AMOXICILLIN 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Diarrhoea, indigestion. • Feeling sick (nausea), vomiting. • White, furry, sore tongue and mouth (oral thrush). 	<p>Speak to your doctor if you have any of these less serious side</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Soreness or itching of the vagina or vaginal discharge (vaginal thrush). • Headache, dizziness, tiredness. • Teeth discolouration. • Unusually active (hyperactivity). 	<p>effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Itching, rash. • Dark urine or pale stools. • Difficulty or pain in passing urine, decreased amount of urine. • Yellowing of the skin or eyes (jaundice). • Severe stomach cramps. • Severe watery or bloody diarrhoea, which may also be bloody. • Unusual bleeding or bruising. • A red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck. 	<p>Tell your doctor immediately if you notice any of these symptoms during or after taking APO-AMOXICILLIN.</p>
<p>Allergic Reactions:</p> <ul style="list-style-type: none"> • Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever. 	<p>Stop taking APO-AMOXICILLIN and call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Remember, you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with APO-AMOXICILLIN.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side-effects from your medicine which are not mentioned here.

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

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

APO-AMOXICILLIN is only available with a doctor's prescription.

What APO-AMOXICILLIN Capsules contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• 250 mg or 500 mg amoxicillin (as trihydrate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Magnesium stearate• Microcrystalline cellulose• Gelatin• Sodium lauryl sulphate• Colloidal anhydrous sulfite• Croscarmellose sodium• Titanium dioxide• Iron oxide yellow• Iron oxide red (500 mg only)• Iron oxide black (500 mg only)• The capsules are printed with TekPrint SW-9008 Black ink
Potential allergens	Contains phenylalanine and sulfites.

APO-AMOXICILLIN does not contain lactose, sucrose, gluten or tartrazine.

Do not take APO-AMOXICILLIN if you are allergic to any of these ingredients.

What APO-AMOXICILLIN Capsules looks like

APO-AMOXICILLIN 250 mg Capsule

Yellow/yellow capsules, with "RX 654" printed in black on both cap and body.

AUST R 208147. Available in pack size of 20 capsules.

APO-AMOXICILLIN 500 mg Capsule

Maroon/yellow capsules with "RX 655" printed in black on both cap and body.

AUST R 208144. Available in pack size of 20 capsules.

Who distributes APO-AMOXICILLIN Capsules

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St,

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in September 2024.