

APO-AMOXYCILLIN

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-AMOXYCILLIN?

APO-AMOXYCILLIN contains the active ingredient amoxicillin (as trihydrate). APO-AMOXYCILLIN is used to treat infections in different parts of the body caused by bacteria.

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

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

Do not take if you have ever had an allergic reaction to APO-AMOXYCILLIN 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 APO-AMOXYCILLIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-AMOXYCILLIN 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-AMOXYCILLIN?

- Follow the instructions provided when APO-AMOXYCILLIN is prescribed, including the number of days it should be taken. APO-AMOXYCILLIN can be taken with or without food.
- Shake the APO-AMOXYCILLIN Suspension in the bottle well, before measuring out the dose in a suitable measure. Make sure that the whole dose is swallowed each time.

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

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking APO-AMOXYCILLIN.• Tell your doctor 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, difficulty breathing, severe diarrhoea or sore white mouth or tongue.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking APO-AMOXYCILLIN, or change the dosage, without checking with your doctor.• Do not give APO-AMOXYCILLIN to anyone else, even if their symptoms seem similar to yours.• Do not take APO-AMOXYCILLIN to treat any other complaints unless your doctor or pharmacist tells you 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-AMOXYCILLIN affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-AMOXYCILLIN in its original packaging until it is time to take it.• Keep APO-AMOXYCILLIN Dry powder in a cool dry place where the temperature will stay below 25°C. Protect it from moisture.• Keep the reconstituted APO-AMOXYCILLIN Suspension in refrigerator (2 to 8°C), do not freeze it. Use it within 14 days. Unused suspension must be discarded after 14 days.

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

6. Are there any side effects?

Less serious side effects are nausea (feeling sick), indigestion, vomiting, oral thrush - white and sore tongue and mouth, vaginal thrush - sore and itchy vagina and/or discharge, teeth discolouration.

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-AMOXICILLIN

Active ingredient: *amoxicillin(as trihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-AMOXICILLIN. **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-AMOXICILLIN or giving it to your child.**

Where to find information in this leaflet:

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

1. Why am I taking APO-AMOXICILLIN?

APO-AMOXICILLIN contains the active ingredient amoxicillin (as trihydrate). Amoxicillin (as trihydrate) is an antibiotic that belongs to a group of medicines called penicillins. It is used to treat infections in different parts of the body caused by bacteria. It works by killing the bacteria that are causing the infection. Amoxicillin (as trihydrate) can also be used to prevent infection.

Amoxicillin (as trihydrate) will not work against infections caused by viruses such as colds or the flu.

Use in children

APO-AMOXICILLIN Suspension is a more suitable form of amoxicillin (as trihydrate) for giving to children than capsules.

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

Warnings

Do not take APO-AMOXICILLIN if:

- you are allergic to amoxicillin (as trihydrate), other penicillins or cephalosporins, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take APO-AMOXICILLIN .

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body, muscle pain or tenderness, joint pain or rash, itching or hives on the skin.

Check with your doctor if you:

- are allergic to any other medicines.
- are allergic to any other substances, such as foods, preservatives or dyes.
- have ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- have any other medical conditions, especially the following:
 - glandular fever (mononucleosis)
 - blood disorders such as leukaemia
 - liver or kidney problems
- take any medicines for any other condition
- are pregnant or plan to become pregnant or are breastfeeding.

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.

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

Your doctor can discuss with you the risks and benefits involved. APO-AMOXICILLIN may be used during pregnancy (Category A). It can pass to your baby through breast milk.

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

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 APO-AMOXICILLIN and affect how it works. These include:

- Medicines used to treat gout (e.g. probenecid or allopurinol).
- Other antibiotics (e.g. tetracyclines).
- The contraceptive pill. As with other antibiotics you may need to use extra birth control methods (e.g. condoms).
- Anticoagulants, used to prevent blood clots (e.g. warfarin).

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?

How much to take

- Your doctor or pharmacist will tell you the dose you will need to take. This depends on your condition and whether or not you are taking any other medicines.
- Follow the instructions provided when APO-AMOXICILLIN is prescribed, including the number of days it should be taken.
- The usual adult dose is 250 mg - 500 mg three times a day.
In children, the usual dosage is 125 mg -250 mg three times daily and may vary depending on the weight of your child.

When to take APO-AMOXICILLIN

- Take it at about the same time each day.
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 APO-AMOXICILLIN

- APO-AMOXICILLIN can be taken with or without food. The effects of APO-AMOXICILLIN are not changed by food.
APO-AMOXICILLIN suspension will be prepared by your pharmacist who checks the seal prior to reconstitution. Shake the bottle well and accurately measure the dose with a suitable measure. Your pharmacist will explain how many millilitres of suspension will be needed to receive the correct dose. Make sure that the whole dose is swallowed each time.

How long to take it for

- Do not stop taking APO-AMOXICILLIN because you are feeling better.
- If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.
- Make sure you have enough to last over weekends and holidays.
- Unused APO-AMOXICILLIN must be discarded after 14 days.

If you forget to take APO-AMOXICILLIN

APO-AMOXICILLIN should be taken regularly at the same time each day.

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.

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.

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:

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

If you take too much APO-AMOXICILLIN, you may feel sick or get 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

Tell your doctor if:

- The symptoms of your infection do not improve within a few days, or if they become worse.
- You develop itching with swelling or skin rash or difficulty breathing. Stop taking APO-AMOXICILLIN and contact your doctor immediately.
- You get severe diarrhoea. Tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after you stop taking APO-AMOXICILLIN. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any anti-diarrhoea medicine without first checking with your doctor.
- You get a sore white mouth or tongue while taking or soon after stopping APO-AMOXICILLIN, or if you get vaginal itching or discharge.
This may mean you have a fungal infection called thrush. Sometimes the use of APO-AMOXICILLIN allows fungi to grow and the above symptoms to occur. APO-AMOXICILLIN does not work against fungi.
- You are about to have any blood tests.
- You become pregnant.
- You are about to start taking any other new medicine.

Remind any doctor, dentist or pharmacist you visit that you are taking APO-AMOXICILLIN.

Keep any appointments with your doctor.

Your doctor may want to do tests to make sure APO-AMOXICILLIN is working and to prevent side effects.

Things you should not do

- Do not stop taking APO-AMOXICILLIN, or change the dosage, without checking with your doctor.
- 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 or pharmacist tells you to.

Driving or using machines

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

APO-AMOXICILLIN generally 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, drowsiness or tiredness in some people.

Looking after your medicine

Keep APO-AMOXICILLIN in the original packaging until it is time to take it. If you take it out of the original packaging it may not keep well.

Keep APO-AMOXICILLIN Dry powder in a cool dry place where the temperature will stay below 25°C. Protect it from moisture.

Keep the reconstituted APO-AMOXICILLIN Suspension in refrigerator (2 to 8°C), do not freeze it. Use it within 14 days. Unused suspension must be discarded after 14 days.

Do not store APO-AMOXICILLIN:

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

Do not take APO-AMOXICILLIN after the expiry date (EXP) printed on the pack. If you take APO-AMOXICILLIN after the expiry date has passed, it may not work as well. Do not take APO-AMOXICILLIN if the packaging is torn or shows signs of tampering or if it does not look quite right. If it has expired or is damaged, return it to your pharmacist for disposal.

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"> Oral thrush - white and sore tongue and mouth. Vaginal thrush - sore and itchy vagina and/or discharge. Diarrhoea. Nausea (feeling sick). Indigestion. Vomiting. Teeth discolouration (especially with the suspension). 	<p>Speak to your doctor if you 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"> Itching or any type of skin rash. Unusual bleeding or bruising. Yellowing of the skin or eyes. Dark urine or pale stools. Difficulty or pain on passing urine. Severe diarrhoea. Feeling hyperactive or having trouble concentrating. 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 the following side effects, even if they occur several weeks after you have stopped taking APO-AMOXICILLIN:</p> <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>These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention.</p> <p>Do not take any anti-diarrhoea medicine without checking with your doctor first.</p>	<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>

Very serious side effects

Very serious side effects	What to do
<p>Allergic reaction including:</p> <ul style="list-style-type: none"> Wheezing, shortness of breath or difficulty breathing. Fainting. Swelling of limbs, face, lips, mouth, tongue or throat which 	<p>You may need urgent medical attention or hospitalisation. Call your doctor straight away,</p>

Very serious side effects	What to do
<p>may cause difficulty swallowing or breathing.</p> <ul style="list-style-type: none"> • Dizziness or convulsions. • Severe abdominal cramps or stomach cramps. 	<p>or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

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

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

What APO-AMOXYCILLIN Suspension contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Amoxicillin (as trihydrate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Saccharin sodium • Colloidal silica anhydrous • Sodium citrate dihydrate • Sorbitol • Sunset yellow FCF • Xanthan gum • Tutti Frutti flavor (PI 183)
Potential allergens	<ul style="list-style-type: none"> • Saccharin • Sodium • Sulfites

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

APO-AMOXYCILLIN Suspension contains sorbitol:

The 125 mg/5 mL strength contains 18 g sorbitol in 120 mL reconstituted suspension.

The 250 mg/5 mL strength contains 7.2 g sorbitol in 60 mL reconstituted suspension. Products containing sorbitol may have a laxative effect or cause diarrhoea.

APO-AMOXYCILLIN 125 mg/5 mL Suspension contains 1.14 mg sodium in 1 mL reconstituted suspension.

APO-AMOXYCILLIN Suspension does not contain lactose, sucrose or tartrazine.

What APO-AMOXYCILLIN Suspension looks like

APO-AMOXYCILLIN Suspension when reconstituted by the pharmacist forms a 100 mL orange suspension, and is available in the following strengths:

APO-AMOXYCILLIN 125 mg/5 mL Suspension

Bottle: AUST R 137882

APO-AMOXYCILLIN 250 mg/5 mL Suspension

Bottle: AUST R 137883

Who distributes APO-AMOXYCILLIN Suspension

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street,

Cremorne, VIC 3121

www.arrotex.com.au

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