

APO-Amoxicillin Capsules

Contains the active ingredient amoxicillin

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about amoxicillin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on the medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Amoxicillin. It contains the active ingredient, amoxicillin (as trihydrate).

It is an antibiotic which used to treat infections in different parts of the body caused by bacteria.

Amoxicillin can also be used to prevent infection.

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

How it works

Amoxicillin is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed amoxicillin for another reason.

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

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you before driving.

Use in children

Amoxicillin Suspension is a more suitable form of amoxicillin than capsules, for giving to children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have had an allergic reaction to:

- amoxicillin
- other penicillins or cephalosporins

- any of the ingredients listed near the end of this leaflet.

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, muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine 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.

If you are not sure whether you should start taking amoxicillin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

1. You are allergic to:

- any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 2. You have ever had an allergic reaction (such as a rash) to any antibiotics in the past.**

3. You have or have had any medical conditions, especially the following:

- glandular fever (mononucleosis)
- blood disorders such as leukaemia
- liver or kidney problems.

4. You are pregnant or plan to become pregnant or breast-feed.

Your doctor can discuss with you the risks and benefits involved. Amoxicillin may be used during pregnancy. It can pass to your baby through breast milk.

5. Your urine has to be tested for sugar levels while taking amoxicillin.

Amoxicillin will produce false positive results when some of these tests are used. Your doctor will help you to identify the correct test.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and amoxicillin may interfere with each other. 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).

These medicines may be affected by amoxicillin, 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 and pharmacist will advise you. They will tell you if you are taking any of

these medicines. They may also have more information on medicines to be careful with or avoid while taking amoxicillin.

How to take this medicine

Follow all directions from your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The usual adult dose is one capsule (250 mg or 500 mg) three times a day.

For some infections 3 grams of amoxicillin (i.e. six 500 mg capsules) can be taken by adults at one time.

How to take it

Swallow amoxicillin capsules whole with a glass of fluid.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

Space the doses as evenly as possible throughout the day.

For example, if you are taking amoxicillin three times a day, take a dose about every eight hours.

Amoxicillin can be taken with or without food. The effects of amoxicillin are not changed by food.

How long to take it for

Continue taking amoxicillin until you finish the pack or until your doctor says so.

Do not stop taking your capsules 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.

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 that 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) or go to the Accident and

Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much amoxicillin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much amoxicillin, you may feel sick or get diarrhoea.

While you are taking this medicine

Things you must do

Tell your doctor if:

1. **The symptoms of your infection do not improve within a few days, or if they become worse.**
2. **You develop itching with swelling or skin rash or difficulty breathing. Stop taking this medicine and contact your doctor immediately.**
3. **You get severe diarrhoea. Tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after you stopped taking 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.

4. **You get a sore white mouth or tongue while taking or soon after stopping amoxicillin, or if you get vaginal itching or discharge.**

This may mean you have a fungal infection called thrush. Sometimes the use of amoxicillin allows fungi to grow and the above symptoms to occur. Amoxicillin does not work against fungi.

5. **You are about to have any blood tests.**
6. **You become pregnant.**
7. **You are about to start taking any other new medicine.**

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking amoxicillin.

Keep any appointments with your doctor. Your doctor may want to do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not stop taking your medicine 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 and be more difficult to treat.

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

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

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

Amoxicillin generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, amoxicillin may cause dizziness, drowsiness or tiredness in some people.

Possible side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

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

Tell your doctor or pharmacist 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
- diarrhoea
- nausea (feeling sick), indigestion or vomiting
- black or brown furry patches on the tongue (rare).

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor as soon as possible if you notice any of the following:

- 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.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing.

This is a very serious side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after you have stopped taking amoxicillin:

- 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.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any anti-diarrhoea medicine without first checking with your doctor.

Other side effects not listed above may occur in some patients.

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

Ask your doctor or pharmacist if you don't understand anything in this list.

Storage and disposal

Storage

Keep amoxicillin in its original packaging until it is time to take it.

If you take the capsules out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from moisture.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Amoxicillin looks like

APO-Amoxicillin capsules are available in two strengths, each in blister packs of 20 capsules:

- 250 mg yellow/yellow capsules, with "RX 654" printed in black
- 500 mg maroon/yellow capsules with "RX 655" printed in black.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Active Ingredient

Each capsule contains either 250 mg or 500 mg of amoxicillin (as trihydrate).

They also contain the following inactive ingredients:

- magnesium stearate
- microcrystalline cellulose
- gelatin
- sodium lauryl sulphate
- colloidal anhydrous silica
- croscarmellose sodium
- titanium dioxide
- iron oxide yellow
- iron oxide red (500 mg only)

- iron oxide black (500 mg only).

APO-Amoxycillin capsules do not contain lactose, sucrose, gluten or tartrazine.

Australian Registration Numbers

APO-Amoxycillin 250 mg capsules blister packs:

AUST R 208147

APO-Amoxycillin 500 mg capsules blister packs:

AUST R 208144

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was last updated in July 2016.