

APO-Amoxycillin and Clavulanic Acid 500 mg/125 mg Tablets

Contains the active ingredients, amoxycillin trihydrate and potassium clavulanate

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

Consumer Medicine Information

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 amoxycillin and clavulanic acid.

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 your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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 your medicine.

You may want to read it again.

What amoxycillin and clavulanic acid is used for

The name of your medicine is APO-Amoxycillin and Clavulanic Acid 500 mg /125 mg Tablets. It contains the active ingredients, amoxycillin and clavulanic acid.

It is used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis or urinary tract infection), sinuses (sinusitis), ears (otitis media), the tonsils (tonsillitis) or the skin.

How it works

Amoxycillin is a type of penicillin antibiotic. Clavulanic acid is used to help the amoxycillin work better against certain types of bacteria.

Amoxycillin and clavulanic acid works by killing the bacteria that cause these infections. It will not work against infections such as colds or the flu, which are caused by viruses.

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

Your doctor may have prescribed amoxycillin and clavulanic acid

tablets for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

These tablets are not recommended for children weighing less than 40 kg. Your doctor will advise you about suitable medicines for children under this weight. The tablets may be used in children weighing 40kg or more.

Before you take amoxycillin and clavulanic acid

When you must not take it

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

- * amoxycillin
- * other penicillins or cephalosporins
- * any of the ingredients listed at 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, throat 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 if you have previously experienced liver problems after taking amoxicillin and clavulanic acid or any other medicines.

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, 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 this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes.

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

- * liver problems
- * kidney problems
- * glandular fever (mononucleosis)
- * leukaemia.

3. You are pregnant or planning to become pregnant.

This medicine is not recommended for use during pregnancy. If there is a need to consider using amoxicillin and clavulanic acid during pregnancy, your doctor will discuss with you the possible risks and benefits of taking it.

4. You are breast-feeding or wish to breast-feed.

Your doctor will discuss with you the possible benefits and risks of

taking this medicine whilst breast-feeding.

5. You have to test your urine for sugar.

This medicine may affect the results of these tests.

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

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 and clavulanic acid may interfere with each other. These include:

- * medicines used to treat gout (e.g. probenecid or allopurinol)
- * other antibiotics. These may interfere with the actions of amoxicillin and clavulanic acid
- * the contraceptive pill.

These medicines may be affected by amoxicillin and clavulanic acid or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Talk to your doctor or pharmacist about the need for an additional method of contraception while taking amoxicillin and clavulanic acid.

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

Your doctor and pharmacist can 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 and clavulanic acid.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by 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 tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of amoxicillin and clavulanic acid 500 mg /125 mg tablets is one tablet twice a day (approximately every 12 hours).

If you have kidney problems you may need to take just one tablet every 24 hours.

Children weighing 40 kg or more may have similar doses to adults. Your doctor will tell you.

How to take it

Swallow the tablet with a full glass of water.

When to take it

Take the tablet immediately before or with the first mouthful of food. This medicine works best when taken this way. It may also help to prevent stomach upsets. However, amoxicillin and clavulanic acid will still work if it is taken without food.

Space the doses as evenly as possible throughout the day.

If you are taking the tablets twice a day, take a dose about every 12 hours.

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.

How long to take it for

Continue taking your medicine until the course is finished or for as long as your doctor tells you.

Do not stop taking it just because you feel better.

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If your next dose is due within six hours, 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) for advice, 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 and clavulanic acid.

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

You may need urgent medical

attention.

If you take too much amoxicillin and clavulanic acid, you may experience nausea, vomiting, cramps and diarrhoea.

While you are taking amoxicillin and clavulanic acid

Things you must do

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

If you are about to start taking any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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 while you are taking amoxicillin and clavulanic acid, do not take any more and contact your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after amoxicillin and clavulanic acid 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.

If you get a sore white mouth or tongue while taking or soon after stopping amoxicillin and clavulanic acid, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of amoxicillin and clavulanic

acid allows fungi to grow and the above symptoms to occur.

Amoxicillin and clavulanic acid does not work against fungi.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

Amoxicillin and clavulanic acid may affect the results of some tests.

Things you must not do

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 if you drink alcohol when you are taking this medicine

Drinking alcohol while taking these tablets does not usually cause any problems. However, some people who drink alcohol while taking antibiotics similar to amoxicillin and clavulanic acid have experienced adverse effects.

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

Generally, these tablets do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, amoxicillin and clavulanic acid may cause dizziness or tiredness in some people. If this occurs, do not drive or operate machinery.

Side effects of amoxicillin and clavulanic acid

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 and clavulanic acid.

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:

- * diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, nausea (feeling sick) or vomiting (being sick)
- * white, furry, sore tongue and mouth (oral thrush), abnormal taste, black hairy tongue
- * soreness or itching of the vagina or vaginal discharge (vaginitis or vaginal thrush), pain when urinating (cystitis)
- * headache, dizziness, tiredness, hot flushes, sinusitis
- * muscle or back pain
- * problems getting to sleep, feeling hyperactive
- * tooth discolouration.

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

Tell your doctor immediately if you notice any of the following during or after finishing a course of amoxicillin and clavulanic acid:

- * itching or any type of skin rash or blistering, peeling or flaking skin
- * dark urine or pale stools
- * yellowing of the skin or eyes

(jaundice)

- * severe stomach cramps
- * severe watery or bloody diarrhoea
- * unusual bleeding or bruising.

These may be serious side effects. You may need medical attention.

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

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:

- * signs of an allergic reaction, such as hives, a severe skin reaction, fainting, swelling of the limbs, face, lips, mouth or throat, difficulty swallowing or breathing
- * a serum-sickness -like reaction shown by fever, general ill feeling, hives, itching, joint pain, rash, swollen lymph nodes
- * fits (convulsions)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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.

After taking this medicine

Storage

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

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees 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.

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 and Clavulanic Acid 500 mg/125 mg looks like

White, convex, capsule shaped film coated tablets.

Available in blister packs of 10 tablets.

Ingredients

Each tablet contains the following active ingredients:

- * 500 mg of amoxicillin (as amoxicillin trihydrate)
- * 125 mg of clavulanic acid (as potassium clavulanate).

It also contains the following

inactive ingredients:

- * microcrystalline cellulose
- * sodium starch glycollate
- * colloidal anhydrous silica
- * magnesium stearate
- * purified talc
- * titanium dioxide
- * methylcellulose
- * diethyl phthalate
- * dimethicone 100

This medicine is gluten-free,
lactose-free, sucrose-free,
tartrazine-free and free of other azo
dyes.

Australian Registration Number

APO-Amoxicillin and Clavulanic Acid 500 mg/125 mg Tablets:

Blister packs

AUST R 153775.

Distributor

Apotex Pty Ltd
66 Waterloo Road
North Ryde, NSW 2113
Australia

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