

Amoxycillin and Clavulanic Acid 500mg/125mg APOTEX Tablets

Amoxicillin trihydrate and potassium clavulanate

Consumer Medicine Information

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

What is in this leaflet

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.

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.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Amoxycillin and clavulanic acid is used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), ears (otitis media) or 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 viral 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 this medicine for another reason.

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

This medicine is not addictive.

These tablets are not recommended for children weighing less than 40 kg.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- amoxicillin
- other penicillins or cephalosporins
- 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, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have previously experienced liver problems after taking amoxycillin and clavulanic acid, or any other medicines.

Do not take this medicine if you have severe kidney problems.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

Tell your doctor if you have to test your urine for sugar.

Amoxycillin and clavulanic acid 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 get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with amoxycillin and clavulanic acid. These include:

- warfarin or other medicines used to prevent blood clots
- medicines used to treat gout (e.g. probenecid, allopurinol)
- other antibiotics used to treat infections
- the contraceptive pill

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Talk to your doctor about the need for an additional method of contraception while taking this medicine.

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

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose is one tablet twice a day (approximately every 12 hours).

How to take it

Swallow the tablet whole with a full glass of water.

The tablets may be broken in half but should not be chewed.

When to take it

Take the tablet immediately before or with the first mouthful of food.

This medicine works best when taken this way and may help to prevent stomach upsets.

Take this medicine at about the same time each day.

Taking it 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.

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

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

It is important to keep taking your medicine even if you feel well. 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 it is almost time to take 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 experiencing side effects.

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 (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

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

You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Take this medicine exactly as your doctor has prescribed.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise your doctor may think that it was not working as it should and change your treatment unnecessarily.

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 amoxycillin 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 amoxycillin 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 amoxycillin and clavulanic acid allows fungi to grow and the above symptoms to occur. Amoxycillin and clavulanic acid does not work against fungi.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you. This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Alcohol should be avoided during and for several days after treatment with this medicine.

Some people who drink alcohol while taking antibiotics similar to amoxycillin and clavulanic acid tablets have experienced adverse effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking amoxycillin and clavulanic acid.

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, but 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.

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

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)
- headache, dizziness, tiredness, hot flushes, sinusitis
- muscle or back pain
- problem getting to sleep, feeling hyperactive
- tooth discolouration.

The above list includes serious side effects that may require medical attention.

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

- 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)
- itching or any type of skin rash or blistering, peeling or flaking skin, which may or may not be accompanied by a fever or swollen lymph nodes
- dark urine or pale stools, yellowing of the skin or eyes (jaundice)
- severe stomach cramps, severe watery or bloody diarrhoea
- unusual bleeding or bruising

The above list includes serious side effects and you may need medical attention.

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

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)
- fever, chills, fatigue, headache and body aches, nausea or vomiting, and sensitivity to light (symptoms of aseptic meningitis)
- inflammation of the bowel (colitis), liver (hepatitis) or kidney (nephritis)
- blood disorders
- crystals in the urine (crystalluria)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

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

Product description

What it looks like

500/125 - Off-white, oval, biconvex, film-coated tablet, scored on both sides.

Available in blister packs of 10 tablets. AUST R 317064.

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:

- magnesium stearate
- purified talc
- povidone
- croscarmellose sodium
- microcrystalline cellulose
- triethyl citrate
- ethylcellulose
- sodium lauryl sulfate
- cetyl alcohol
- hypromellose
- titanium dioxide.

Contains 24.5 mg potassium per tablet. This medicine does not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in September 2021.