

# APO-AMOXY/CLAV 500/125 & APO-AMOXY/CLAV 875/125

## 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 using APO-AMOXY/CLAV?

APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 contain the active ingredients amoxicillin and clavulanic acid and are used for the short term treatment of a wide range of infections caused by bacteria. For more information, see Section [1. Why am I using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#) in the full CMI.

### 2. What should I know before I use APO-AMOXY/CLAV?

Do not use if you have ever had an allergic reaction to amoxicillin trihydrate, potassium clavulanate, penicillin or similar types of antibiotics (such as cephalosporins), 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 use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 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 use APO-AMOXY/CLAV?

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 use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#) in the full CMI.

### 5. What should I know while using APO-AMOXY/CLAV?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you are using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125</li><li>• Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 affect you</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcohol should be avoided during and for several days after treatment</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Protect from moisture and store below 25°C</li></ul>

For more information, see Section [5. What should I know while using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include nausea, vomiting, pruritis or urticaria. Serious side effects include itching, rash, dark urine or pale stools, yellowing of the skin or eyes (jaundice), severe stomach cramps, severe watery or bloody diarrhoea, unusual bleeding or bruising or allergic reactions. All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

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-AMOXY/CLAV 500/175 & APO-AMOXY/CLAV 875/125

Active ingredient(s): *amoxicillin trihydrate and potassium clavulanate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125.**

Where to find information in this leaflet:

- [1. Why am I using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#)
- [2. What should I know before I use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#)
- [5. What should I know while using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?

**APO-AMOXY/CLAV 500/125 and APO-AMOXY/CLAV 875/125 contain the active ingredients amoxicillin and clavulanic acid.**

APO-AMOXY/CLAV 500/125 and APO-AMOXY/CLAV 875/125 belong to the penicillin group of antibiotics and work by killing bacteria that cause infections. They will not work against infections caused by viruses such as colds or the flu.

**APO-AMOXY/CLAV 500/125 and APO-AMOXY/CLAV 875/125 tablets are used for the short term treatment of a wide range of infections caused by bacteria. These infections may affect the chest (e.g. bronchitis or pneumonia), bladder (e.g. cystitis), sinuses (e.g. sinusitis), the ears (e.g. otitis media) or the skin.**

Your doctor may prescribe APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets for another use. If you want more information, ask your doctor.

There is no evidence that APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets are addictive.

## 2. What should I know before I use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?

### Warnings

**Do not use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 if:**

- you are allergic to amoxicillin trihydrate, potassium clavulanate, 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.
- you have previously experienced liver problems after taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 or any other medicines.
- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed

Always check the ingredients to make sure you can use this medicine.

Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.

If you are not sure whether you should start taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets, talk to your doctor.

### 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 experienced liver problems after taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets or any other medicines.
- have glandular fever (mononucleosis) or leukemia.
- have any kidney or liver problems.
- have to test your urine for sugar (APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets may affect the results of these tests)

The dosage of APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 may need to be changed or you may need to be given an alternative medicine.

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 will discuss with you the possible risks and benefits of taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 during pregnancy or while you are breast-feeding.

APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 can pass 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:

- warfarin or other medicines used to prevent blood clots
- mycophenolate
- medicines used to treat gout (eg. probenecid or allopurinol).
- other antibiotics (these may interfere with the actions of APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125).
- contraceptive pill (as with other antibiotics, you may need to use extra birth control methods (eg. condoms) while taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125).

**Some medicines may interfere with [medicine name] 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-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125.**

### **4. How do I use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?**

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 this medicine, talk to your doctor or pharmacist.

### **How much to take / use**

Swallow the APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablet with a full glass of water or other liquid.

APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets should be taken immediately before or with the first mouthful of food. APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets work best when taken this way. It may also prevent stomach upsets.

However, APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets will still work if they are taken without food.

### **When to take / use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125**

- Space the doses as evenly as possible throughout the day.
- If you are taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 tablets twice a day, take a dose about every twelve hours.

### **How long to take APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 for**

Keep taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 until the course is finished or for as long as your doctor tells you.

Do not stop taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 just because you feel better as the infection can return.

Do not stop taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125, or change the dose, without first checking with your doctor.

### **If you forget to use APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125**

APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 should be used regularly at the same time each day.

If your next dose is due within six hours, 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 your tablets 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 use too much APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125**

If you think that you have used too much APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125, 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.

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

## 5. What should I know while using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125?

### Things you should do

Take APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 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.

Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125.

Remind any doctor, dentist or pharmacist you visit that you are using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 before starting any other medicines.

Some medicines may affect the way other medicines work.

### Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use to treat any other complaints unless your doctor says to.
- Do not stop using this medicine until the course is finished or for as long as your doctor tells you.

### Things to be careful of

- If you develop severe diarrhoea either when taking APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 or within several weeks after treatment, tell your doctor as soon as possible.
- Do not take any medication to stop the diarrhoea (eg. Lomotil® or Imodium®).

Remind any doctor, dentist or pharmacist you visit that you are using APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 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, APO-AMOXY/CLAV 500/125

or APO-AMOXY/CLAV 875/125 may cause dizziness or tiredness in some people.

### Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol should be avoided during and for several days after treatment with APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125.

Some people who drink alcohol while taking antibiotics similar to APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 have experienced adverse effects.

### Looking after your medicine

- Store below 25°C
- Keep your tablets in the original pack until it is time to take them

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, 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 use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine 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"><li>• diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick</li><li>• nausea, vomiting</li><li>• white, furry, sore tongue and mouth (oral thrush), abnormal taste</li><li>• soreness or itching of the vagina or vaginal discharge (vaginal thrush)</li><li>• headache, dizziness, tiredness, hot flushes</li><li>• tooth discolouration</li><li>• unusually active (hyperactivity)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>itching, rash</li><li>dark urine or pale stools</li><li>yellowing of the skin or eyes (jaundice)</li><li>severe stomach cramps</li><li>severe watery or bloody diarrhoea</li><li>unusual bleeding or bruising</li></ul> <p>Rare events:</p> <ul style="list-style-type: none"><li>inflammation of the bowel (colitis)</li><li>inflammation of the liver (hepatitis)</li><li>inflammation of the kidney (nephritis)</li><li>blood disorders</li><li>crystals in the urine (crystalluria)</li></ul>	<b>Tell your doctor immediately if you notice any of these symptoms during or after taking.</b>
<ul style="list-style-type: none"><li>fits/seizures</li><li>aseptic meningitis</li></ul> <p>Allergic reactions:</p> <ul style="list-style-type: none"><li>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</li></ul>	<b>Stop taking and 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.</b>

**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](http://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

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

### What APO-AMOXY/CLAV 500/125 or APO-AMOXY/CLAV 875/125 contains

<b>Active ingredient (main ingredient)</b>	amoxicillin 500 mg clavulanic acid 125 mg
<b>Other ingredients (inactive ingredients)</b>	magnesium stearate croscarmellose sodium talc-purified microcrystalline cellulose  The tablet coating on the tablets contains: titanium dioxide hypromellose ethylcellulose dichloromethane hydroxypropylcellulose isopropyl alcohol propylene glycol
<b>Potential allergens</b>	Contains 25 mg potassium per tablet

**Do not take this medicine if you are allergic to any of these ingredients.**

### What APO-AMOXY/CLAV 500/125 looks like

APO-AMOXY/CLAV 500/125 tablets come as white, oval shaped, film coated tablet with marking "CA625" on one side (AUST R 255075).

### What APO-AMOXY/CLAV 875/125 looks like

APO-AMOXY/CLAV 875/125 tablets come as white elongated capsule shaped film coated tablet (AUST R 255080).

### Who distributes APO-AMOXY/CLAV 500/125 and APO-AMOXY/CLAV 875/125

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel St  
Cremorne VIC 3121  
[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in January 2024.