APX-AMOXICILLIN/CLAVULANIC ACID 500/125
APX-AMOXICILLIN/CLAVULANIC ACID 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 taking APX-AMOXICILLIN/CLAVULANIC ACID?

APX-AMOXICILLIN/CLAVULANIC ACID contains the active ingredients amoxicillin and clavulanic acid.

APX-AMOXICILLIN/CLAVULANIC ACID is used for the short term treatment of a wide range of infections caused by bacteria.

For more information, see Section 1. Why am I taking APX-AMOXICILLIN/CLAVULANIC ACID? in the full CMI.

2. What should I know before I take APX-AMOXICILLIN/CLAVULANIC ACID?

Do not take 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 take APX-AMOXICILLIN/CLAVULANIC ACID? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-AMOXICILLIN/CLAVULANIC ACID 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 APX-AMOXICILLIN/CLAVULANIC ACID?

- 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 take APX-AMOXICILLIN/CLAVULANIC ACID? in the full CMI.

5. What should I know while taking APX-AMOXICILLIN/CLAVULANIC ACID?

Things you should do	• Take APX-AMOXICILLIN/CLAVULANIC ACID exactly as your doctor has prescribed. • Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. • Remind any doctor, dentist or pharmacist you visit that you are taking APX-AMOXICILLIN/CLAVULANIC ACID. • Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting APX-AMOXICILLIN/CLAVULANIC ACID.
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.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how APX-AMOXICILLIN/CLAVULANIC ACID affects you.
Drinking alcohol	• Alcohol should be avoided during and for several days after treatment with APX-AMOXICILLIN/CLAVULANIC ACID.
Looking after your medicine	• Keep your tablets in the original pack until it is time to take them. • Store it in a cool dry place, away from moisture where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking APX-AMOXICILLIN/CLAVULANIC ACID? in the full CMI.

6. Are there any side effects?

The most common side effects of APX-AMOXICILLIN/CLAVULANIC ACID are diarrhoea, nausea and vomiting.

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.

APX-AMOXICILLIN/CLAVULANIC ACID 500/125
APX-AMOXICILLIN/CLAVULANIC ACID 875/125

Active ingredients: *amoxicillin trihydrate and potassium clavulanate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APX-AMOXICILLIN/CLAVULANIC ACID. **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 APX-AMOXICILLIN/CLAVULANIC ACID.**

Where to find information in this leaflet:

1. Why am I taking APX-AMOXICILLIN/CLAVULANIC ACID?
2. What should I know before I take APX-AMOXICILLIN/CLAVULANIC ACID?
3. What if I am taking other medicines?
4. How do I take APX-AMOXICILLIN/CLAVULANIC ACID?
5. What should I know while taking APX-AMOXICILLIN/CLAVULANIC ACID?
6. Are there any side effects?
7. Product details

1. Why am I taking APX-AMOXICILLIN/CLAVULANIC ACID?

APX-AMOXICILLIN/CLAVULANIC ACID contains two active ingredients. One of these is a penicillin called amoxicillin and the other is potassium clavulanic.

APX-AMOXICILLIN/CLAVULANIC ACID belongs to the penicillin group of antibiotics.
APX-AMOXICILLIN/CLAVULANIC ACID is 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 APX-AMOXICILLIN/CLAVULANIC ACID for another use. If you want more information, ask your doctor.
There is no evidence that APX-AMOXICILLIN/CLAVULANIC ACID is addictive.

2. What should I know before I take APX-AMOXICILLIN/CLAVUANIC ACID?

Warnings

Do not take APX-AMOXICILLIN/CLAVULANIC ACID 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 APX-AMOXICILLIN/CLAVULANIC ACID or any other medicines.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

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.

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 APX-AMOXICILLIN/CLAVULANIC ACID or any other medicines.
- have glandular fever (mononucleosis) or leukaemia.
- have any kidney or liver problems.
  The dosage of APX-AMOXICILLIN/CLAVULANIC ACID may need to be changed or you may need to be given an alternative medicine.
- have to test your urine for sugar.
  APX-AMOXICILLIN/CLAVULANIC ACID may affect the results of these tests.

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 APX-AMOXICILLIN/CLAVULANIC ACID during pregnancy or while you are breast-feeding. APX-

AMOXICILLIN/CLAVULANIC ACID 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 (e.g. probenecid or allopurinol).
- other antibiotics. These may interfere with the actions of APX-AMOXICILLIN/CLAVULANIC ACID.
- methotrexate (a medicine used to treat cancer or rheumatic diseases).
- contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking APX-AMOXICILLIN/CLAVULANIC ACID.

Some medicines may interfere with APX-AMOXICILLIN/CLAVULANIC ACID 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 APX-AMOXICILLIN/CLAVULANIC ACID.

4. How do I take APX-AMOXICILLIN/CLAVUANIC ACID?

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

Swallow APX-AMOXICILLIN/CLAVULANIC ACID tablet with a full glass of water or other liquid.

When to take APX-AMOXICILLIN/CLAVULANIC ACID

APX-AMOXICILLIN/CLAVULANIC ACID should be taken immediately before or with the first mouthful of food. APX-AMOXICILLIN/CLAVULANIC ACID works best when taken this way. It may also help to prevent stomach upsets. However, APX-AMOXICILLIN/CLAVULANIC ACID will still work if taken without food.

Space the doses as evenly as possible throughout the day. If you are taking APX-AMOXICILLIN/CLAVULANIC ACID twice a day, take a dose about every twelve hours.

How long to take it for

Keep taking APX-AMOXICILLIN/CLAVULANIC ACID until the course is finished or for as long as your doctor tells you.

Do not stop taking APX-AMOXICILLIN/CLAVULANIC ACID just because you feel better as the infection can return.

Do not stop taking APX-AMOXICILLIN/CLAVULANIC ACID, or change the dose, without first checking with your doctor.

If you forget to take APX-AMOXICILLIN/CLAVULANIC ACID

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 take too much APX-AMOXICILLIN/CLAVULANIC ACID

If you think that you have taken too much APX-AMOXICILLIN/CLAVULANIC ACID, 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.

Symptoms of overdose include mild to severe nausea, vomiting, cramps and diarrhoea.

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

5. What should I know while taking APX-AMOXICILLIN/CLAVUANIC ACID?

Things you should do

Take APX-AMOXICILLIN/CLAVULANIC ACID 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 APX-AMOXICILLIN/CLAVULANIC ACID.

Remind any doctor, dentist or pharmacist you visit that you are taking APX-AMOXICILLIN/CLAVULANIC ACID 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.

Things to be careful of

If you develop severe diarrhoea either when taking APX-AMOXICILLIN/CLAVULANIC ACID or within several weeks after treatment, tell your doctor as soon as possible. Do not take any medication to stop the diarrhoea (e.g. Lomotil® or Imodium®).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APX-AMOXICILLIN/CLAVULANIC ACID affects you.

Generally, this medicine does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, APX-AMOXICILLIN/CLAVULANIC ACID may cause dizziness or tiredness in some people.

Drinking alcohol

Alcohol should be avoided during and for several days after treatment with APX-AMOXICILLIN/CLAVULANIC ACID. Some people who drink alcohol while taking antibiotics similar to APX-AMOXICILLIN/CLAVULANIC ACID have experienced adverse effects.

Looking after your medicine

Keep your tablets in the original pack until it is time to take them. If you take the tablets out of its original pack it may not keep well.

Store in a cool dry place, away from moisture where the temperature stays below 25°C. 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
• Diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick. • Nausea, vomiting. • White, furry, sore tongue and mouth (oral thrush), abnormal taste. • Soreness or itching of the vagina or vaginal discharge (vaginal thrush). • Headache, dizziness, tiredness, hot flushes. • Tooth discolouration. • Unusually active (hyperactivity).	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Itching, rash. • fever • Dark urine or pale stools. • Yellowing of the skin or eyes (jaundice). • Severe stomach cramps. • Severe watery or bloody diarrhoea. • Unusual bleeding or bruising. • anaemia Rare Events: • Inflammation of the bowl (colitis). • Inflammation of the liver (hepatitis). • Inflammation of the kidney (nephritis). • Blood disorders. • Crystals in the urine (crystalluria).	**Tell your doctor immediately if you notice any of these symptoms during or after taking APX-AMOXICILLIN/CLAVULANIC ACID.**
• Fits/seizures. • Aseptic meningitis. • A red rash commonly seen on both sides of the buttocks, upper inner thighs, armpits, neck. • A red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck Allergic Reactions: • Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or	**Stop taking APX-AMOXICILLIN/CLAVULANIC ACID and call your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever.	

Remember, you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with APX-AMOXICILLIN/CLAVULANIC ACID.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side-effects from your medicine which are not mentioned here.

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

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

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

What APX-AMOXICILLIN/CLAVULANIC ACID contains

Active ingredient (main ingredient)	**APX-AMOXICILLIN/CLAVULANIC ACID 500/125** • 500 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate) **APX-AMOXICILLIN/CLAVULANIC ACID 875/125** 875 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate)
Other ingredients (inactive ingredients)	• Magnesium stearate • Purified talc • Povidone • Croscarmellose sodium • Microcrystalline cellulose • Triethyl citrate • Ethylcellulose • Sodium lauryl sulfate • Cetyl alcohol • Hypromellose • Titanium dioxide
	APX-AMOXICILLIN/CLAVULANIC ACID 875/125 also contains silicon dioxide.
Potential allergens	APX-AMOXICILLIN/CLAVULANIC ACID 500/125 and APX-AMOXICILLIN/CLAVULANIC ACID 875/125 contains 25 mg potassium per tablet.

APX-AMOXICILLIN/CLAVULANIC ACID 500/125 and APX-AMOXICILLIN/CLAVULANIC ACID 875/125 does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

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

What APX-AMOXICILLIN/CLAVULANIC ACID looks like

APX-AMOXICILLIN/CLAVULANIC ACID 500/125 is an off-white, oval biconvex, film-coated tablet, scored on both sides (AUST R 351832).

Available in strip pack of 10 tablets.

APX-AMOXICILLIN/CLAVULANIC ACID 875/125 is a white to pale yellow, oblong biconvex, film-coated tablet, scored on both sides (AUST R 351833).

Available in strip pack of 10 tablets.

Who distributes APX-AMOXICILLIN/CLAVULANIC ACID

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St,

Cremorne VIC 3121

www.arrotex.com.au

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