

## APX-Amoxicillin/Clavulanic acid 500/125; APX-Amoxicillin/Clavulanic acid 875/125

amoxicillin trihydrate and potassium clavulanate tablets

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125.

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 taking 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 need to read it again.

#### WHAT APX-AMOXICILLIN/CLAVULANIC ACID 500/125 and APX-AMOXICILLIN/CLAVULANIC ACID 875/125 ARE USED FOR

This medicine contains two active ingredients. One of these ingredients is a type of penicillin called amoxicillin and the other is potassium clavulanate.

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

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that this medicine is addictive.

#### How it works

APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 work by killing the bacteria that cause these infections. It will not work against infections caused by viruses such as colds or the flu.

#### BEFORE YOU TAKE APX-AMOXICILLIN/CLAVULANIC ACID 500/125 or APX-AMOXICILLIN/CLAVULANIC ACID 875/125

##### When you must not take it

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

- amoxicillin trihydrate or potassium clavulanate, the active ingredients, or similar types of antibiotics (e.g. penicillins, cephalosporins, carbapenems or monobactams) or any of the inactive ingredients mentioned at the end of this leaflet, under Product Description.

Some of the 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
- rash, itching or hives on the skin.

**Do not take this medicine if you have or have had any of the following medical conditions:**

- liver 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 the pharmacist for disposal.

**If you are not sure whether you should start to take 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 are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor will discuss the risks and benefits involved. Amoxicillin and potassium clavulanate pass into breast milk. The effect on breastfed infants is not known.

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

- kidney disease
- liver disease
- glandular fever (mononucleosis), leukaemia or blood disorder.

**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 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 APX-Amoxicillin/Clavulanic acid 500/125 or APX-Amoxicillin/Clavulanic acid 875/125 may interfere with each other. These include:

- medicines to treat gout (probenecid or allopurinol)
- oral contraceptives ("The Pill")
- other antibiotics
- anticoagulants
- mycophenolate
- methotrexate, a medicine used to treat arthritis and some type of cancer.

These medicines may be affected by APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 or may affect how well they work. You may need to use different amounts of your medicines, or 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 APX-AMOXICILLIN/CLAVULANIC ACID 500/125 and APX-AMOXICILLIN/CLAVULANIC ACID 875/125

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

They may differ from the information contained in this leaflet.

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

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

##### How much to take

Your doctor will tell you how many tablets you need to take. This will depend on the type of infection you have.

##### Adults

Usual dose - one APX-Amoxicillin/Clavulanic acid 500/125 tablet every 12 hours.

For severe infections one tablet every 12 hours of APX-Amoxicillin/Clavulanic acid 875/125 is used.

These dosages may vary depending on your conditions and the severity of your illness.

##### Children

Children weighing 40 kg and more should be dosed according to adult recommendations.

APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 tablets are not recommended for children weighing less than 40 kg.

##### How and when to take it

**APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 tablets should be taken immediately before or with the first mouthful of food.**

If you take it on an empty stomach, it may cause stomach upset.

##### How long to take it

**Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.**

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

##### If you forget to take your dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**Do not take a double dose to make up for the dose you missed.**

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when 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) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much APX-Amoxicillin/Clavulanic acid 500/125 or APX-Amoxicillin/Clavulanic acid 875/125. Do this even if there are no signs of discomfort or poisoning.**

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

You may need urgent medical attention.

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## WHILE YOU ARE TAKING APX-AMOXICILLIN/ CLAVULANIC ACID 500/125 or APX-AMOXICILLIN/ CLAVULANIC ACID 875/125

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### *Things you must do*

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 in breathing while you are taking this medicine, stop taking it 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 you have stopped taking this medicine.**

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 this medicine, 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 this medicine causes fungi to grow and the above symptoms to occur. APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 do not work against fungi.

**Do not drink alcohol while you are taking APX-Amoxicillin/Clavulanic acid 500/125 or APX-Amoxicillin/Clavulanic acid 875/125.**

If you drink alcohol while taking this medicine you may not feel well.

Always follow your doctor's instructions carefully.

Tell your doctor if you are pregnant or plan to become pregnant while taking this medicine.

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

**If you have to test your urine for sugar while you are being given this medicine, make sure your doctor knows which type of test you use.**

APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 may affect the results of some of these tests.

**If you have to have any blood tests tell your doctor you are taking this medicine.** APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking this medicine.

### *Things you must not do*

**Do not stop taking this medicine without your doctor's permission.**

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.

Do not take this medicine to treat any other complaint unless your doctor says so.

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

### *Things to be careful of*

**Be careful driving or operating machinery until you know how this medicine affects you.**

APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, they may cause dizziness or drowsiness in some people. Make sure you know how you react to the medicine before you drive a car, operate machinery or do anything that may be dangerous if you are affected.

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## SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need urgent 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:**

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- mild diarrhoea
- feeling sick or vomiting
- abdominal pain or indigestion
- rash and itching
- aseptic meningitis
- dizziness
- headache
- inability to sleep
- aching muscles, muscle tenderness or weakness
- back pain
- tiredness
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache
- superficial tooth discolouration
- hot flushes
- unusually active (hyperactive).

These are the more common side effects of APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125. Mostly, these are mild and short-lived.

**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:**

- severe diarrhoea with blood, mucus, stomach pain and fever
- severe body rash with pinkish, itchy swellings of the skin (hives or nettle rash)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of your skin or eyes (jaundice)
- fits or seizures
- unusual bleeding or bruising under the skin
- dark urine or pale stools
- shortness of breath, wheezing or difficulty in breathing
- severe blisters and bleeding of the lips, eyes, mouth, nose and genitals.

**Rare events that have been reported with APX-Amoxicillin/Clavulanic acid 500/125 and APX-Amoxicillin/Clavulanic acid 875/125 include:**

- inflammation of the bowel (colitis)
- inflammation of the liver (hepatitis)
- inflammation of the kidney (nephritis)
- blood disorders
- crystals in the urine (crystalluria)

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

Other side effects not listed above may also occur in some people.

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## AFTER TAKING APX-AMOXICILLIN/ CLAVULANIC ACID 500/125 or APX-AMOXICILLIN/ CLAVULANIC ACID 875/125

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**Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with this medicine:**

- 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 diarrhoea medicine without first checking with your doctor.**

### *Storage*

Keep your medicine in the original container. If you take the tablets out of its original container it may not keep well.

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

**Do not store APX-Amoxicillin/Clavulanic acid 500/125 or APX-Amoxicillin/Clavulanic acid 875/125 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 tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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## PRODUCT DESCRIPTION

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### *What it looks like*

APX-Amoxicillin/Clavulanic acid comes in two strengths:

- APX-Amoxicillin/Clavulanic acid 500/125 - Off-white, oval, biconvex, film-coated tablet, scored on both sides.
- APX-Amoxicillin/Clavulanic acid 875/125 - White to pale yellow, oblong, biconvex, film-coated tablet, scored on both sides.

Available in strip packs of 10 tablets.

### *Ingredients*

Active Ingredients:

- APX-Amoxicillin/Clavulanic acid 500/125 tablets - 500 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).
- APX-Amoxicillin/Clavulanic acid 875/125 tablets - 875 mg amoxicillin (as trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

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.

APX-Amoxicillin/Clavulanic acid 500/125 and 875/125 contain 25 mg potassium per tablet. This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

### *Supplier*

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park, NSW 2113  
Australia  
Tel: (02) 8877 8333

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### **Australian Register Numbers**

APX-Amoxicillin/Clavulanic acid 500/125 tablets: AUST R 351832 (strip packs)

APX-Amoxicillin/Clavulanic acid 875/125 tablets: AUST R 351833 (strip packs)