

# APO-Amoxicillin and Clavulanic Acid 875mg/125mg

## Tablets

*Contains the active ingredients amoxicillin trihydrate and potassium clavulanate*

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### Consumer Medicine Information

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

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#### What is in this leaflet

##### **Read this leaflet carefully before taking your medicine.**

This leaflet answers some common questions about amoxicillin 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. More recent information on this medicine may be available.

##### **Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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#### What this medicine is used for

The name of your medicine is APO-Amoxicillin and Clavulanic Acid 875mg/125mg tablets. It contains the active ingredients, amoxicillin 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), sinuses (sinusitis), ears (otitis media) or skin.

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.

##### *How it works*

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

Amoxicillin 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.

There is no evidence that this medicine is addictive.

##### *Use in children*

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

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#### Before you take this medicine

##### *When you must not take it*

**Do not take this medicine if you are hypersensitive to, or have had an allergic reaction to:**

- **amoxicillin**
- **other penicillins or cephalosporins**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor**

**immediately or go to the Accident and Emergency department at the nearest hospital.**

- **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 if you have severe kidney problems.**
- **Do not take this medicine if the expiry date (EXP) printed on the pack has passed.**
- Do not take this medicine if the packaging is torn, shows signs of tampering or it does not look quite right.

### *Before you start to take it*

**Before you start taking this medicine, 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 currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available

from your pharmacy, supermarket or health food shop.

Some medicines may interact with amoxicillin and clavulanic acid.

These include:

- warfarin or other medicines used to prevent blood clots
- 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with amoxicillin and clavulanic acid.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

### *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 of amoxicillin and clavulanic acid 875/125 tablets is one tablet twice a day (approximately every 12 hours).

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

### *How to take it*

**Swallow the tablet 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. It may also help to prevent stomach upsets.

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 this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

### *How long to take it for*

Continue taking your medicine 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 it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.**

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

### *If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident**

**and Emergency department at your nearest hospital.**

**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**

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

### *Things you must not do*

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor

### *Things to be careful of*

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

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking amoxicillin and clavulanic acid or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor if you notice any of the following:**

- 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.

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

These may be serious side effects and you may need medical attention:

- 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.

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

### *Allergic reactions*

**If you think you are having an allergic reaction to amoxicillin and clavulanic acid, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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### *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°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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

- microcrystalline cellulose
- crospovidone
- carmellose sodium
- hydroxypropylcellulose
- magnesium stearate
- titanium dioxide
- colloidal anhydrous silica
- purified talc
- triethyl citrate
- polysorbate 80
- ethylcellulose.

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

### *Australian Registration Number*

AUST R 163696.

### *Sponsor*

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113  
Australia

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## Product description

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### *What APO-Amoxycillin and Clavulanic Acid 875/125 looks like*

White to off-white, oblong, film-coated tablets. The tablets are scored and debossed with 875/125 on one side and AMC on the other side.

Available in blister packs of 10 tablets.

### *Ingredients*

Each tablet contains the following active ingredients:

- 875 mg of amoxycillin (as amoxycillin trihydrate)
- 125 mg of clavulanic acid (as potassium clavulanate).

It also contains the following inactive ingredients: