Co-amoxiclav 500 mg/125 mg film-coated tablets (Amoxicillin/Clavulanic acid)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet
1. What Co-amoxiclav is and what it is used for
2. What you need to know before you take Co-amoxiclav
3. How to take Co-amoxiclav
4. Possible side effects
5. Missed doses
6. Contents of the pack and other information

1. What Co-amoxiclav is and what it is used for
Co-amoxiclav is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Co-amoxiclav is used in adults and children to treat the following infections:
- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

2. What you need to know before you take Co-amoxiclav

Do not take Co-amoxiclav if any of the above apply to you.
- if you are allergic to amoxicillin, clavulanic acid, penicillins or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- Do not take Co-amoxiclav if any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before taking Co-amoxiclav.

Warnings and precautions
Talk to your doctor or pharmacist before taking Co-amoxiclav if you:
- have glaucoma
- are being treated for liver or kidney problems
- are not passing water regularly
- If you are not sure if some of the above apply to you, talk to your doctor or pharmacist before taking Co-amoxiclav.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Co-amoxiclav or a different medicine.

Conditions you need to look out for
Co-amoxiclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for these symptoms while you are taking Co-amoxiclav, to reduce the risk of any problems. See “Conditions you need to look out for” in section 4.

Blood and urine tests
If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Co-amoxiclav. This is because Co-amoxiclav can affect the results of these types of tests.

Other medicines and Co-amoxiclav
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are taking allopurinol (used for gout) with Co-amoxiclav, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-amoxiclav.

If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav then extra blood tests may be needed.

3. How to take Co-amoxiclav

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over
The recommended dose is:
- 1 tablet three times a day

Children weighing less than 40 kg
Children aged 6 years or less should preferably be treated with amoxicillin/clavulanic acid oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Co-amoxiclav tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Patients with kidney and liver problems
If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.

- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Co-amoxiclav
Take with a meal
Swallow the tablets whole with a glass of water.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Co-amoxiclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Co-amoxiclav than you should
If you take too much Amoxicillin/Clavulanic acid, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible.

Keep this medicine carton or bottle to show the doctor.

If you forget to take Co-amoxiclav
If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-amoxiclav
Keep talking Co-amoxiclav until your treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

- skin rash
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- Sore throat, swelling of the lips, tongue or throat (angioedema), causing difficulty in breathing
- Collapse
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- Contact a doctor immediately if you get any of these symptoms. Stop taking Co-amoxiclav.

5. Missed doses
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6. Contents of the pack and other information

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- Check with your doctor or pharmacist if you are not sure.

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- If you have liver problems you may have more frequent blood tests to check how your liver is working.

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- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Co-amoxiclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

- If you take more Co-amoxiclav than you should
- If you take too much Amoxicillin/Clavulanic acid, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible.

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- Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

- Conditions you need to look out for

- Allergic reactions:
- skin rash
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- Sore throat, swelling of the lips, tongue or throat (angioedema), causing difficulty in breathing
- Collapse
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- Contact a doctor immediately if you get any of these symptoms. Stop taking Co-amoxiclav.

- Inflammation of large intestine
Inflammation of the large intestine, causing difficulty in breathing usually with blood and mucus, stomach pain and/or fever.

- Acute inflammation of the pancreas (acute pancreatitis)
If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis. Drugs-induced enterocolitis syndrome (DIES): DIIES has been reported mainly in children receiving amoxicillin/clavulanic. It is a rare kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

Co-amoxiclav can affect how methotrexate (a medicine used to prevent the rejection of transplanted organs) works.

Co-amoxiclav can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Co-amoxiclav can have side effects and the symptoms may make you unfit to drive.

Don’t drive or operate machinery unless you are feeling well.

Amoxicillin/Clavulanic acid contains sodium:
This medicine contains up to 9.3 mg (0.23 mg per tablet, that is to say essentially sodium-free).
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-amoxiclav tablets contains
- The active substances are amoxicillin trihydrate and potassium clavulanate.
- Each film-coated tablet contains amoxicillin trihydrate equivalent to 500mg amoxicillin with potassium clavulanate equivalent to 125mg clavulanic acid.
- The other ingredients are:
  - Core: Microcrystalline cellulose (E460), colloidal anhydrous silica, magnesium stearate (E470b), sodium starch glycolate (Type A).
  - Film coating: Hypromellose (E464), macrogol 400, titanium dioxide (E171).

What Co-amoxiclav tablets look like and contents of the pack
Film-coated tablets.
Co-amoxiclav 500/25 mg tablets are white, oval, film-coated tablets inscribed with ‘A’ on one side and ‘64’ on the other side.
Co-amoxiclav tablets are available in Alu/Alu (polyamide/PVC - aluminium foil) blister packs with 4/5/6/7/8/10/12/14/15/16/20/21/24/25/30/35/40/50/100/500 film-coated tablets. Not all listed pack sizes will be marketed.

Marketing Authorisation Holder
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Manufacturer
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Advice/medical education
Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.
Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.
Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carelessly can help to reduce the chance of bacteria becoming resistant to them.
When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.
1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. You should only ever use antibiotics prescribed by your doctor for any of the reasons given above.