

CO-AMOXICLAV 250/125 mg TABLETS (Amoxicillin and Clavulanic Acid)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or for your child). Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Co-Amoxiclav is and what it is used for
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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 substance (clavulanic acid) stops this from happening.

Co-Amoxiclav is used in adults and children to treat the following infections:

- sinus infections
- urinary tract infections
- skin infections
- dental infections.

2 Before you take Co-Amoxiclav

Do NOT take Co-Amoxiclav:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of Co-Amoxiclav (listed in section 6)
- if you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Co-Amoxiclav.

Take special care with Co-Amoxiclav

Talk to your doctor or pharmacist before taking Co-Amoxiclav if you:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above applies to you, speak to your doctor or pharmacist before taking Co-Amoxiclav. 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 certain symptoms while you are taking this medicine to reduce the risk of any problems. See 'Conditions you need to look out for' see 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), tell the doctor or nurse that you are taking Co-Amoxiclav. This is because Co-Amoxiclav can affect the results of these kinds of tests.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

- If you are taking allopurinol (used for gout) with Co-Amoxiclav, you may be more likely to 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
- Co-Amoxiclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works
- Co-Amoxiclav may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Taking Co-Amoxiclav with food and drink:

It is recommended that you take Co-Amoxiclav 250/125 mg Tablets at the start of meals to reduce any possible digestive discomfort.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant or are breast-feeding, please tell your doctor or pharmacist.

This medicine passes into breast milk in small quantities and may affect breast-fed infants. Ask your doctor for further advice.

Driving and using machines

Co-Amoxiclav can have side effects and the symptoms, such as dizziness, may make you unfit to drive. Don't drive or operate machinery unless you are sure you are not affected.

3 How to take Co-Amoxiclav

Always take Co-Amoxiclav 250/125 mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over

The usual dose is:

One tablet three times a day. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Swallow each tablet whole with a glass of water at the start of a meal or slightly before. Do not break, crush or divide a tablet in half.

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Co-Amoxiclav oral suspension or sachets.

Co-Amoxiclav tablets are not recommended.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or 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.

Haemodialysis Patients

Two Co-Amoxiclav 250/125 mg Tablets every 24 hours, during and at the end of the dialysis.

Do not take this medicine for more than 2 weeks. If you still feel unwell you should speak to your doctor.

If you take more Co-Amoxiclav than you should:

If you take too much of this medicine, signs of an overdose are: feeling or being sick, diarrhoea, abdominal pain, convulsions (fits). Talk to your doctor as soon as possible. Take the medicine carton or blister strip with you to show the doctor.

If you forget to take Co-Amoxiclav

If you forget to take a dose of this medicine, take the forgotten dose as soon as you remember. But do not take the next dose too soon, there must be a minimum of 4 hours between two doses.

Do not take a double dose to make up for the forgotten individual dose.

If you stop taking Co-Amoxiclav

Keep taking this medicine until the treatment is finished, even if you feel better. If you stop taking this medicine too soon, the infection may come back. Also, the bacteria may become resistant to the medicine. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Co-Amoxiclav can cause side effects, although not everybody gets them.

If any of the following side effects occur, stop taking Co-amoxiclav and go to the hospital at once:

- Allergic reactions such as:
 - 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
 - swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
 - collapse.
- Serious skin reactions such as:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blistering (*exanthematous pustulosis*)
 - a skin rash which may blister and look like a small target (a central dark spot surrounded by a paler area, with a dark ring around the edge – erythema multiforme).
- Inflammation of the large intestine causing watery diarrhoea usually with blood and mucus, stomach pain and /or fever
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Jaundice, caused by increased bilirubin in the blood (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow.

Very common side effects - (affect more than 1 in 10 people)

- diarrhoea (in adults).

Common side effects - (affect up to 1 in 10 people)

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high dosages -if affected take Co-Amoxiclav before food
- vomiting (being sick)
- diarrhoea (children).

Uncommon side effects - (affect up to 1 in 100 people)

- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in blood tests:

- increase in some substances (enzymes) produced by the liver.

Rare side effects that may show up in your blood tests (affect up to 1 in 1,000 people):

- low number of cells involved in blood clotting
- low number of white blood cells.

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- inflammation of the liver (hepatitis)
- inflammation of tubes in the kidneys
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Co-Amoxiclav or who have kidney problems)
- black tongue which looks hairy.

Side effects that may show up in blood or urine tests:

- severe reduction in the numbers of white blood cells
- a low number of red blood cells (*haemolytic anaemia*)
- crystals in the urine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Co-Amoxiclav

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original container.

Do not use Co-Amoxiclav after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Co-Amoxiclav if the tablets are chipped or damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information**What Co-Amoxiclav contains:**

The active substances are amoxicillin and clavulanic acid.

- 250 mg amoxicillin as amoxicillin trihydrate
- 125 mg clavulanic acid as potassium clavulanate

Other ingredients are: Magnesium stearate (E572), povidone, talc, croscarmellose sodium, microcrystalline cellulose, triethyl citrate, ethyl cellulose, sodium lauryl sulphate, cetyl alcohol, hypromellose, and titanium dioxide (E171).

What Co-Amoxiclav looks like and contents of the pack:

Each tablet is oblong, convex and off-white in colour. The tablets are scored on both sides. Co-Amoxiclav 250/125 mg Tablets are supplied in blister packs of 15 or 21 tablets and hospital packs of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

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