

PACKAGE LEAFLET: INFORMATION FOR THE USER**Co-amoxiclav 500/125 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 further 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 in 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. How to store Co-amoxiclav
6. Contents of the pack and other information

1. What Co-amoxiclav is and what it is used for

The name of your medicine is Co-amoxiclav 500/125 mg film-coated tablets but it will be referred to as Co-amoxiclav in the rest of this leaflet.

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 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 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 applies to you. 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 this medicine 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, 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 certain 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 taking, have recently taken or might take 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.
- 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.
- Methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.
- Co-amoxiclav may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy and breast-feeding and fertility

If you are pregnant, you think you might be pregnant, or are planning to have a baby or if you are breast-feeding, please tell your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any 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.

This medicine contains Sodium:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Co-amoxiclav

Always take Co-amoxiclav 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

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.

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 different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check your liver is working.

Method of administration

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before.
- 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 Co-amoxiclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the 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 around 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 taking Co-amoxiclav until the 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

The side effects below may happen with this medicine.

400 mm

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, amplit or groin
- swelling, sometimes of the face or mouth (*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 and stop taking Co-amoxiclav.

Inflammation of large intestine:

- Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Drug-induced enterocolitis syndrome (DIES):

DIES has been reported mainly in children receiving amoxicillin/clavulanic acid. It is a certain 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.

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.

Contact your doctor as soon as possible for advice if you get these symptoms:

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

- diarrhoea (in adults)

Common side effects (may 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 doses
 - if affected take Co-amoxiclav before food
- vomiting
- diarrhoea (in children)

Uncommon side effects (may 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 your blood tests:

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

Rare side effects (may affect up to 1 in 1000 people)

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - *erythema multiforme*)
 - If you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

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

Not known (frequency cannot be estimated from the available data):

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain and spinal cord (*aseptic meningitis*)
- Serious skin reactions:
 - 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 blisters (*exanthematous pustulosis*)

- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).

Contact a doctor immediately if you get any of these symptoms.

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- inflammation of the liver (hepatitis)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- 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 your blood or urine tests:

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine leading to acute renal injury

Reporting of side effects

If you get any side effects, talk to your doctor or 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-amoxiclav

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not throw 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 contains

- The active substances are amoxicillin and clavulanic acid.
- Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.
- The other ingredients are:
 - **Tablet core:** microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, butyl-hydroxytoluene (E321), talc and magnesium stearate.
 - **Film-coat:** hypromellose, titanium dioxide (E171), talc, macrogol 400, isopropyl alcohol and purified water.

What Co-amoxiclav looks like and contents of the pack

- Co-amoxiclav tablets are white to off-white oval shaped, biconvex, film-coated tablets with "BL-625" debossed on one side of the tablet. They are packaged in blister packs of 10, 12, 14, 15, 16, 20, 21, 40 or 50 tablets, enclosed in a carton.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Name and address: Crescent Pharma Ltd.
Key House, Sarum Hill,
Basingstoke, RG21 8SR, UK.
Telephone: 01256 772 730
E-mail: Safety@crestpharma.com

Manufacturer

Name and address: Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire, HP4 1EG
United Kingdom
Telephone: 0044 (0) 1442 200922
E-mail: info@bristol-labs.co.uk

Co-amoxiclav 500/125mg film-coated tablets;
PL 20416/1055

This leaflet was last revised in February 2026.

To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or telephone, email) above.

V13 06-02-25 00