

PACKAGE LEAFLET

Package leaflet: Information for the user

Co-amoxiclav 250mg/125mg film-coated Tablets Co-amoxiclav 500mg/125mg 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. 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 leaflets. See section 4.

What is in this leaflet:

1. What Co-amoxiclav Tablets are and what they are used for
2. What you need to know before you take Co-amoxiclav Tablets
3. How to use Co-amoxiclav Tablets.
4. Possible side effects
5. How to store co-amoxiclav tablets
6. Content of the pack and other information

1. What Co-amoxiclav Tablets are and what they are 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: *250 mg/125 mg film-coated tablets:*

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

500 mg/125 mg film-coated tablets:

- 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 Tablets

Do not take Co-amoxiclav:

- if you are allergic to amoxicillin, clavulanic acid, penicillin 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. If you are not sure, talk to your doctor or pharmacist before taking Co-amoxiclav Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-amoxiclav Tablets 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 apply to you, talk to your doctor or pharmacist before taking these tablets.

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 Tablets

Tell your doctor or pharmacist if you are using, have recently used or might use 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, 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.

Co-amoxiclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

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

This medicine contains 0.63 mmol (or 24.632 mg) potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Pregnancy and breast-feeding

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.

3. How to take Co-amoxiclav Tablets

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

250 mg/125 mg film-coated tablets:

The usual dose is 1 tablet three times a day

500 mg/125 mg film-coated tablets:

The usual dose is 1 tablet three times a day

Children weighing less than 40 kg

Co-amoxiclav tablets are not recommended.

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 Tablets

- 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 Tablets than you should

If you take too much Co-amoxiclav Tablets, 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 Tablets

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 Tablets

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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
- swelling, sometimes of the face 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 Tablets**.

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea 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.

Drug-induced enterocolitis syndrome (DIES): DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

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

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These 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 with a meal.

- vomiting.
- diarrhoea (in children)

Uncommon side effects

These 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

These 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.

Frequency not known

Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- 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 (*exanthemous 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))
 - Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)
- Crystals in urine leading to acute kidney injury

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

- 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 eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Co-amoxiclav Tablets 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.

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 ([see details below](#)). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Co-amoxiclav Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Do not take this medicine after the expiry date which is stated on the carton and blister strip after EXP. The expiry date refers to the last day of that month.

Do not take this medicine if you notice any visible signs of deterioration.

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., Diluted

250mg/125mg Tablets: Each film-coated tablet contains 250mg amoxicillin as amoxicillin trihydrate and 125mg of clavulanic acid as potassium clavulanate, diluted.

500mg/125mg Tablets: Each film-coated tablet contains 500mg amoxicillin as amoxicillin trihydrate and 125mg of clavulanic acid as potassium clavulanate, diluted.

- The other ingredients are:

Cellulose, microcrystalline (E460)

Sodium starch glycolate, Type A

Silica, Colloidal anhydrous (E551)

Magnesium Stearate (E572)

Film coat

Titanium dioxide (E171)
Hypromellose (E464)
Propylene glycol (E1520)
Talc (E553b)
Ethyl cellulose

What Co-amoxiclav looks like and contents of the pack

250mg/125mg Tablets: White, capsule shaped, film coated tablet debossed with '1 05' on one side and plain on the other.

500mg/125mg Tablets: White, capsule-shaped film-coated tablet, debossed with '1 06' on one side and plain on the other.

The tablets are packaged in aluminium blisters consisting of: 4, 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 25, 30, 35, 40, 50, 100 & 500 tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder

Brown & Burk IR Limited
22 Northumberland Road,
Ballsbridge, Dublin 4,
Ireland

Manufacturer

Micro Labs GmbH
Lyoner Straße 14
60528 Frankfurt
Deutschland

Misom Labs Limited
Malta Life Sciences Park,
LS2.01.06, Industrial Estate,
San Gwann, SGN 3000,
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

UK(NI) & IE: Co-amoxiclav 250mg/125mg Film-coated Tablets & Co-amoxiclav 500mg/125mg Film-coated Tablets

SE: Amoxicillin/Clavulanic acid BB 250mg/125mg filmdragerade tablett & Amoxicillin/Clavulanic acid BB 500mg/125mg filmdragerade tablett

DE & AT: Amoxicillin/Clavulansäure Micro Labs 250 mg/125 mg & 500 mg/125 mg Filmtabletten

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