

PACKAGE LEAFLET

Package leaflet: Information for the patient

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 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

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 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 neck.
- 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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-amoxiclav. This is especially important 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 this medicine.

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 this medicine, 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.

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) and mycophenolate mofetil (a medicine used after organ transplants) work.

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

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

Adults and children weighing 40 kg and over

- The usual 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 (in bottle or sachets).

Ask your doctor or pharmacist for advice when giving Co-amoxiclav tablets to children weighing less than 40 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

- 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 about 4 hours before taking the next 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 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 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. **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.

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 use). 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 this applies to you, take Co-amoxiclav before food
- 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.

Other side effects

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

- 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))

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 the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- seizures/convulsions (in people taking high doses of amoxicillin/clavulanic acid or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing
- inflammation of the brain membranes (aseptic meningitis)
- inflammation of the bile duct (cholangitis).
- pain in the chest.
- 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)

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

- severe reduction in the number of white blood cells
- lower number of red blood cells (haemolytic anaemia)
- crystals in urine leading to acute kidney injury.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-amoxiclav

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture.

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

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

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 contains

- The active substances are amoxicillin trihydrate and potassium clavulanate. Each film-coated tablet contains amoxicillin trihydrate corresponding to 500 mg amoxicillin and potassium clavulanate corresponding to 125 mg clavulanic acid.
- The other ingredients are:

Core:

Microcrystalline cellulose (E460), colloidal silicon dioxide, magnesium stearate (E470b), sodium starch glycolate (Type A)

Film coating:

Hypromellose (E464), macrogol 400, titanium dioxide (E171).

What Co-amoxiclav looks like and contents of the pack

Film-coated tablets.

Co-amoxiclav 500 mg/125 mg tablets are white, oval, 20.2 mm x 9.8 mm film-coated tablets inscribed with 'A' on one side and '64' on the other side.

Co-amoxiclav 500 mg/125 mg are available in blister packs with 4/5/6/7/8/10/12/14/15/16/20/21/25/30/35/40/50/100/500 film-coated tablets. Not all listed pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Milpharm Limited
Ares, Odyssey Business Park, West End Road, South Ruislip HA4 6QD
United Kingdom

APL Swift Services Ltd
HF26, Hal Far Industrial Estate
BBG3000, Birzebbugia
Malta

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

IE Co-amoxiclav 500mg/125mg - 875mg/125mg Film-coated Tablets
UK Co-amoxiclav 500/125mg - 875/125mg Film-coated Tablets

This leaflet was last revised in February 2023