

Package leaflet: Information for the user

**Co-Amoxiclav 375mg and 625mg Tablets
(amoxicillin and 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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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. Co-amoxiclav 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 Tablets are used in adults and children to treat the following infections:

- Sinus infections
- Urinary tract infections
- Skin and tissue infections
- Dental infections

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

Do not take Co-amoxiclav Tablets if:

- You are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- 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.

- You have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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 Tablets if:

- You have glandular fever
- You are being treated for liver or kidney problems
- You 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 Co-amoxiclav 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 Tablets or a different medicine.

Conditions you need to look out for

Co-amoxiclav Tablets 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 Tablets, 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 Tablets. This is because Co-amoxiclav Tablets 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.

- If you are taking allopurinol (used for gout) with Co-amoxiclav Tablets, it may be more likely that you will have an allergic skin reaction
- Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended
- If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav Tablets 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 Tablets may 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,

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ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Co-amoxiclav Tablets can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Co-amoxiclav Tablets contain potassium and quinoline yellow (E104)

This medicine contains 24.6 mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains quinoline yellow (E104). May cause allergic reactions.

Sodium content

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 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.

Take at regular intervals. Complete the prescribed course unless otherwise directed.

You should always take these tablets as prescribed by your doctor. The instructions are usually on the pharmacist's label. If you're not sure about anything please ask your doctor or pharmacist.

For infections:

Dosage for adults (including the elderly) and children over 12:

The usual dose is 375mg three times a day, preferably every 8 hours, for a maximum of 14 days.

For more severe infections:

One 625mg tablet three times a day.

For dental infections:

The usual dose is 375mg three times a day, preferably every 8 hours, for 5 days.

Patients with liver or kidney 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.

Use in children

These tablets are not suitable for children under 12 or weighing less than 40kg.

How to take Co-amoxiclav Tablets

- Swallow the tablets whole with a glass of water at the beginning of a meal.
- Do not break or chew the tablets.
- 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 many 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, then carry on with the next dose. 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 Tablets

Keep taking Co-amoxiclav Tablets 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. 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
- 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.

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 administration). 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.

Other side effects

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 you are affected, take Co-amoxiclav Tablets 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)
- Inflammation of the membranes that surround 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 (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)).
- 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 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 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 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 Tablets

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

Do not use this medicine after the expiry date stated on the carton and label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture. Keep the container tightly closed.

6. Contents of the pack and other information

What Co-Amoxiclav Tablets contain

The active substances are amoxicillin (as trihydrate) and clavulanic acid (as potassium clavulanate).
Each Co-amoxiclav 375 mg Tablet contains 250 mg amoxicillin and 125 mg clavulanic acid.
Each Co-amoxiclav 625mg Tablet contains 500 mg amoxicillin and 125 mg clavulanic acid.

The other ingredients are microcrystalline cellulose, quinoline yellow (E104), titanium dioxide (E171), crospovidone, povidone K25, colloidal silicon dioxide, stearic acid, polyethylene glycol 6000, methylhydroxypropylcellulose, saccharin sodium, vanilla flavour and magnesium stearate.

What Co-amoxiclav Tablets look like and contents of the pack

Co-amoxiclav 375mg Tablets are pale yellow, oblong, biconvex tablets embossed 375 on one side.
Co-amoxiclav 625mg Tablets are pale yellow, oblong, biconvex tablets embossed 625 on one side.
Co-amoxiclav Tablets are available in brown glass bottles in packs of 21 tablets.

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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 carefully 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. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.