

- 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 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, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

How to store Co-amoxiclav Tablets Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Do not take Co-amoxiclav tablets after the expiry date which is stated on the carton and blister cap after EXP. The expiry date refers to the last day of that month.

Do not take Co-amoxiclav Tablets if you notice any visible signs of deterioration. 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.

Contents of the pack and other information

What Co-amoxiclav tablets contains:

- The active substances are Amoxicillin Trihydrate and Potassium Clavulanate, Dihydrate

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

500mg/125mg Tablets Each film-coated

tablet contains 500mg amoxicillin as amoxicillin trihydrate and 125mg of clavulanic acid as potassium clavulanate, dihydrate.

The other ingredients are:

- Cellulose, microcrystalline (E460)
- Sodium starch glycolate, Type A
- Silica, Colloidal anhydrous (E511)
- Magnesium Stearate (E572)
- Hyromellose (E464)
- Propylene glycol (E1520)
- Titanium dioxide (E171)
- Hydroxypropyl methylcellulose (HPMC)
- Talc (E553b)
- Ethylcellulose

What Co-amoxiclav looks like and contents of the pack

250mg/125mg Tablets, White, capsule shaped, film coated tablet debossed with '1 00' on one side and plain on the other.

500mg/125mg Tablets, White, capsule-shaped film-coated tablet, debossed with '1 00' on one side and plain on the other.

The tablets are packaged in aluminium blister strips consisting of 4, 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 25, 30, 35, 40, 50, 100 & 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burck UK Ltd
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Horsfield West
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TW4 5DD
UK

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

UK & IE: Co-amoxiclav 250mg/125mg Film-coated Tablets & Co-amoxiclav 500mg/125mg Film-coated Tablets
SE: Amoxicillin/Clavulanic acid BB
250mg/125mg Film-coated tablet &

Amoxicillin/Clavulanic acid BB 500mg/125mg Film-coated tablet
This leaflet was last approved on 04.07.2017

PL01014AC LUB 0208

BROWN & BURCK
Package leaflet: Information for the user
Co-amoxiclav 250mg/125mg film-coated Tablets
Co-amoxiclav 500mg/125mg film-coated Tablets
(Amoxicillin/trihydrate and potassium clavulanate)

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 leaflet. See section 4.

What is this leaflet for?

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

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What Co-amoxiclav Tablets 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 and 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: 250mg/125mg film-coated tablets:

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

Conditions you need to look out for:

Co-amoxiclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions,

- urinary tract infections
- skin and soft tissue infections including dental infections,
- bone and joint infections.

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

- 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 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 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 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

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 alcohol (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, their 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 organs) works.

This medicine contains 0.63 mmol (or 24.62 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, you think you might be pregnant 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 may have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. How to take Co-amoxiclav Tablets

Always take Co-amoxiclav 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

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 **not** be treated with amoxicillin/clavulanic acid oral suspension or tablets.

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 Tablets

- 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 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.

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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone 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, amp or groin
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse.

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.

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

- throat 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

These may affect up to 1 in 100 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)
- 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)

Other 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 (exanthema subitum)

Inflammation of the protective membrane surrounding the brain (meningoencephalitis)

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