

#### 4 Contents of the pack and other information

##### What Co-amoxiclav Tablets contain

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

Each film-coated tablet contains 875mg amoxicillin as amoxicillin trihydrate and 125mg of clavulanic acid as potassium clavulanate, diluted

- The other ingredients are:

Cellulose, microcrystalline (E400)  
Sodium starch glycolate, Type A  
Silica, Colloidal anhydrous (E501)  
Magnesium Stearate (E470b)

##### Film coat

Titanium dioxide (E171)  
Hydroxypropylcellulose (E444)  
Macrogol

What Co-amoxiclav looks like and contents of the pack  
White, oblong-shaped film-coated tablet, debossed with '107' 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, 36, 42, 50, 100 & 500 tablets

Not all pack sizes may be marketed

##### Marketing Authorisation Holder and Manufacturer

Brown & Burck Ltd  
5 Murray Close  
Horsfield West  
Midlothian  
TW8 1DQ  
UK

This medicinal product is authorised in the Member States of the EEA under the following names:  
UK & E: Co-amoxiclav 875mg/125mg Film-coated Tablets  
SE: Amoxicillin Clavulanat BB 875mg/125mg film-coated tablet

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#### Package leaflet: Information for the user Co-amoxiclav 875mg/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 only. Do not pass it on to others. It may harm them, even if the 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

- What Co-amoxiclav Tablets are and what it is used for
- What you need to know before you take Co-amoxiclav Tablets
- How to take Co-amoxiclav Tablets
- Possible side effects
- How to store Co-amoxiclav Tablets
- Contents of the pack and other information

##### 1. 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' 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 Tablets

**Do not take Co-amoxiclav:**  
• if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillins or any of the other ingredients of Co-amoxiclav tablets (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 gout or liver
- are being treated for liver or kidney problems
- are on ongoing water therapy

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 have side effects and the symptoms may make you unwell. 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 reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-amoxiclav.

Co-amoxiclav can affect how myophospholite mesal (a medicine used to prevent the rejection of transplanted organs) works.

This medicine contains 0.63 mmol (or 24.032 mg) potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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

Like all medicines, this medicine can cause side effects which may affect your ability to drive or operate machinery unless you are feeling well.

##### 5. How to take Co-amoxiclav Tablets

Always take Co-amoxiclav Tablets exactly as your doctor has said to you. You should check with your doctor or pharmacist if you are not sure.

##### Adults and children weighing 40 kg and over

Usual dose: 1 tablet twice a day  
Higher dose: 1 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.

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 20 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 shortly 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 Tablets 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 out of the 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 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
- throat pain, swollen glands in the neck, enlarged or swollen, sometimes of the face or mouth (glandular), causing difficulty breathing or collapse.

Warning: Allergic reactions can sometimes occur suddenly.

##### 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.

##### 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 (fits)
- feeling sick (nausea), especially when taking high doses

If affected take Co-amoxiclav before food

- Diarrhoea (in children)

##### Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised body temperature
- indigestion
- dizziness
- headache

##### 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 pale ring, 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 white blood cells
- 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 (Steven-Johnson syndrome), and a more severe form causing extensive peeling of the skin more than 30% of the body surface - toxic epidermal necrolysis)

• a widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)

- a red, scaly rash with bumps under the skin and blisters over the nose and mouth (erythema multiforme)

• Inflammation of the protective membrane surrounding the brain (meningitis)

**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
- hypocalcaemia (in people taking high doses of Co-amoxiclav or who have kidney problems)
- back lumps which look 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 via the Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://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 strip 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.