

Patient Information Leaflet

Co-Amoxiclav 375mg and 625mg Tablets

What you should know about this medicine. Please read this leaflet carefully before you start to take these tablets. If there is something you don't understand, or if you have any other questions remember to ask your pharmacist or doctor. Keep this leaflet, you may want to read it again.

The name of this medicine is Co-amoxiclav Tablets. These tablets are available in two strengths.

Co-amoxiclav Tablets 375mg are pale yellow, biconvex tablets embossed 375 on one side. The tablets contain two active ingredients, 250mg of amoxicillin (as trihydrate) and 125mg clavulanic acid (as potassium clavulanate). (These ingredients together are known as Co-amoxiclav).

Co-amoxiclav Tablets 625mg are pale yellow, oblong, biconvex tablets embossed 625 on one side. The tablets contain 500mg of amoxicillin (as trihydrate) and 125mg clavulanic acid (as potassium clavulanate).

Both strengths of tablets also contain 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.

Co-amoxiclav Tablets 375mg and Co-amoxiclav Tablets 625mg are available as packs of 21 tablets.

How does this medicine work?

Amoxicillin is an antibiotic. Antibiotics are used to treat infections caused by bacteria. When amoxicillin is combined with clavulanic acid it is effective against a wider range of bacteria than when used alone.

Product Licence Holder:

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland

Manufactured by:

Cimex AG, Birsweg 2, CH-4253 Liesburg, Switzerland.

Distributed by:

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR.

Why am I taking Co-amoxiclav Tablets?

They are used to treat respiratory tract infections such as bronchitis, pneumonia, sinusitis, tonsillitis and middle ear infections; infections of the kidneys, abdomen and lower urinary tract including cystitis; and skin and tissue infections.

Make sure that it is safe for you to take these tablets

Sometimes it may not be suitable. You should check with your doctor if:

- you are sensitive or allergic to Co-amoxiclav Tablets or any of the ingredients, or to penicillin or other antibiotics
- you have ever developed serious liver problems when taking an antibiotic,
- you are pregnant, trying to become pregnant, or breast-feeding,
- you have liver or kidney problems,
- you have glandular fever,
- you are on a low potassium diet.

Some drugs will interfere with the action of Co-amoxiclav. Tell your doctor if you are taking any of these medicines

- other antibiotics such as chloramphenicol, erythromycin, sulfonamides, or tetracyclines,
- warfarin or other drugs to prevent blood clotting. The effect of drugs to thin the blood such as warfarin may be increased by Co-amoxiclav. If this happens there could be a risk of excessive bleeding.
- Allopurinol or probenecid for gout and related conditions.

Co-amoxiclav Tablets 375mg and 625mg contain 24.6mg potassium and so may be harmful to people who need to be on a low potassium diet.

Co-amoxiclav Tablets do not interact with oral contraceptives and you should use other methods of contraception whilst taking these tablets.

You should always let your doctor know what other medicines you are taking, including any that have been prescribed by your doctor or you have bought.

Taking your medicine

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.

The dose for people with severe liver or kidney problems may be less than these doses. The doctor will have decided what dose you need.

- These tablets are not suitable for children under 12 or weighing less than 40kg.
- Do not take more tablets than the doctor told you to take. Take the tablets for as long as the doctor told you to. Do not stop taking them because you feel better.
- If you are still unwell after finishing the course of tablets go and see your doctor.
- Swallow the tablets with a drink at the beginning of a meal. Do not break or chew the tablets.

If you forget to take a tablet take one as soon as you remember, then carry on with the next dose.

Try to wait about 4 hours before taking the next dose, and do not take two doses within about one hour or so. Never double-up on the dose to make up for the one you have missed.

If you take too many tablets tell your doctor or the nearest hospital casualty department straight away. Let people know what you have taken.

Are there any side-effects?

Most people do not have any problems when they take these tablets, but nearly all medicines can cause side-effects in some people.

Co-amoxiclav Tablets can sometimes cause stomach problems such as nausea (feeling sick), vomiting, indigestion or diarrhoea. These symptoms are usually mild and can be reduced by taking the tablets at the beginning of a meal.

Very rarely, some people experience hyperactivity, dizziness, headache and convulsions. These symptoms are reversible.

There have been rare reports of tooth discolouration. This can usually be removed by brushing.

Some people may get thrush (a yeast infection of the vagina or mouth) when they take these tablets.

You can get treatments for thrush from your pharmacist or doctor. If you notice anything else which you don't understand ask your doctor or pharmacist's advice.

Some people can be allergic to antibiotics and can develop a rash. This can range in severity from a mild itchy rash to a rarer more serious condition which may cause ulceration of the mouth, lips and skin. Inflammation of the kidney can also occur rarely. In very rare cases, allergic reactions can include difficulty in breathing, fainting or swelling of the face and throat. Stop taking the tablets and tell your doctor if you develop any of these symptoms.

See your doctor immediately if you develop any of the following either while you are taking Co-amoxiclav Tablets or in the weeks after finishing the treatment.

- Severe or prolonged diarrhoea with bleeding
- Darker urine or paler faeces
- Your skin or eyes becoming yellow
- Fever, bruising or bleeding.

Co-amoxiclav Tablets can sometimes affect blood cell counts. Make sure that your doctor knows that you are taking these tablets if you are having blood tests.

How to keep your tablets

Keep all medicines in a safe place away from children.

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

Do not take the tablets after the date shown on the pack.

REMEMBER this medicine was prescribed for you. You should not give it to anyone else even if you think their symptoms are similar. It may harm them.