PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-amoxiclav 500mg/125mg Film-coated Tablets

Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start taking this medicine.
- 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 (or for your child). Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Co-amoxiclav 500 mg/125 mg is and what it is used for
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1. WHAT CO-AMOXICLAV 500 mg/125 mg IS AND WHAT IT IS USED FOR

Co-amoxiclav 500 mg/125 mg 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 500 mg/125 mg 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. BEFORE YOU TAKE CO-AMOXICLAV 500 mg/125 mg

Do not takeCo-amoxiclav 500 mg/125 mg:
- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Co-amoxiclav 500 mg/125 mg (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 500 mg/125 mg if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Co-amoxiclav 500 mg/125 mg.

Take special care with Co-amoxiclav 500 mg/125 mg

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 Co-amoxiclav 500 mg/125 mg.
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 500 mg/125 mg 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 500 mg/125 mg, 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 500 mg/125 mg. This is because Co-amoxiclav 500 mg/125 mg can affect the results of these types of tests.

Using other medicines
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 allopurinol (used for gout) with Co-amoxiclav 500 mg/125 mg, it may be more likely that you'll have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-amoxiclav 500 mg/125 mg

If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav 500 mg/125 mg then extra blood tests may be needed.

Co-amoxiclav 500 mg/125 mg can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Co-amoxiclav 500 mg/125 mg may affect how mycophenolate mofetil (a medicine used to prevent the rejection of new organs in transplant patients) works.

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 500 mg/125 mg 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 500 mg/125 mg
Always take Co-amoxiclav 500 mg/125 mg 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
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 oral suspension.

Ask your doctor or pharmacist for advice when giving Co-amoxiclav 500 mg/125 mg 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 500 mg/125 mg
- 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 500 mg/125 mg for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Co-amoxiclav 500 mg/125 mg than you should
If you take too much Co-amoxiclav 500 mg/125 mg, 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 500 mg/125 mg
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 500 mg/125 mg
Keep taking Co-amoxiclav 500 mg/125 mg 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, Co-amoxiclav 500 mg/125 mg 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.

➔ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Co-amoxiclav 500 mg/125 mg.**

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
- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses

→ if affected take Co-amoxiclav 500 mg/125 mg 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)
- Inflammation of the protective membrane surrounding the brain (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*).

➔ **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
- convulsions (in people taking high doses of Co-amoxiclav 500 mg/125 mg or who have kidney problems)

- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing.

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.

If you get side effects
➔ **Tell your doctor or pharmacist** if any of the side effects become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE CO-AMOXICLAV 500 mg/125 mg
Do not store above 25°C. Store in the original package.

Keep out of the reach and sight of children.

Do not use Co-amoxiclav 500 mg/125 mg tablets after the expiry date (EXP) which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

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.

6. FURTHER INFORMATION
What Co-amoxiclav 500 mg/125 mg contains
The active substances are amoxicillin and clavulanic acid. Each film-coated tablet contains amoxicillin trihydrate equivalent to 500mg of amoxicillin and potassium clavulanate equivalent to 125mg of clavulanic acid. Amoxicillin is an antibiotic and clavulanic acid is a beta lactamase inhibitor, which is commonly combined with the penicillin group antibiotics to overcome antibiotic resistance.

The other ingredients in the tablets are –
Tablet core: magnesium stearate (E572), sodium starch glycollate, colloidal anhydrous silica, microcrystalline cellulose (E460).
Film coating: titanium dioxide (E171), hypromellose (E464), macrogol and dimeticone.

Each tablet contains 0.8mg of sodium.

What Co-amoxiclav 500 mg/125 mg looks like and contents of the pack
Co-amoxiclav 500mg/125mg Film-coated Tablets are white to off white oval shaped, film coated tablets debossed with 'AC' and a score line on one side and plain on the other side.

Co-amoxiclav 500mg/125mg Film-coated Tablets come in packs of 6, 21, 30, 50, 100 and 500 tablets. The 21 pack is a blister pack and the other packs sizes are in glass bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary.

Manufacturer:
SmithKline Beecham Pharmaceuticals, Worthing, West Sussex, United Kingdom.

This leaflet was last approved in 01/2014.

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.