CO-AMOXICLAV 250/125 mg TABLETS
(Amoxicillin and 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What Co-Amoxiclav 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 substance (clavulanic acid) stops this from happening. Co-Amoxiclav is used in adults and children to treat the following infections:
• skin infections
• urinary tract infections
• skin infections
• dental infections.

2. Before you take Co-Amoxiclav
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 this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Co-Amoxiclav.

Take special care with Co-Amoxiclav
Talk to your doctor or pharmacist before taking Co-Amoxiclav 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 applies to you, speak to your doctor or pharmacist before taking Co-Amoxiclav. 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 this medicine to reduce the risk of any problems. See 'Conditions you need to look out for' (see Section 4).

3. How to take Co-Amoxiclav
Always take Co-Amoxiclav 250/125 mg 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
The usual dose is:
One tablet three times a day. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Swallow each tablet whole with a glass of water at the start of a meal or slightly before. Do not break, crush or divide a tablet in half.

Children weighing less than 40 kg
Children aged 6 years or less should preferably be treated with Co-Amoxiclav oral suspension or sachets. Co-Amoxiclav tablets are not recommended.

Patients with kidney and liver 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.

Haemodialysis Patients
Two Co-Amoxiclav 250/125 mg Tablets every 24 hours, during and at the end of the dialysis.

Do not take this medicine for more than 2 weeks. If you still feel unwell you should speak to your doctor.

How to take Co-Amoxiclav than you should:
• If you take too much of this medicine, sign of an overdose are: feeling or being sick, diarrhea, abdominal pain, convulsions (fits). Talk to your doctor as soon as possible. Take the medicine carton or blister strip with you to show the doctor.

4. Possible side effects
Common side effects
• indigestion
• raised itchy rash (hives)
• diarrhoea (children).
These include:
• allergic reactions, convulsions (fits) and inflammation of the large intestine.
• a low number of red blood cells
• severe reduction in the numbers of white blood cells
• a skin rash which may blister and looks like a hot, red rash
• widespread red skin rash with small blisters
• fever, joint pain, swollen glands in the neck.
Other side effects
• blood takes longer to clot
• blood cell status tests or liver function tests
• haemolytic anaemia
• fever, joint pain, swollen glands in the neck
• skin rash
• raised itchy rash (hives)
• diarrhoea, abdominal pain, convulsions (fits).

5. Possible side effects

Other side effects
• a low number of red blood cells
• severe reduction in the numbers of white blood cells
• a skin rash which may blister and looks like a hot, red rash
• widespread red skin rash with small blisters
• fever, joint pain, swollen glands in the neck.

6. What to do if you forget to take your medicine
If you forget to take Co-Amoxiclav, take the forgotten dose as soon as you remember. Do not take a double dose to make up for the forgotten individual dose.

Taking Co-Amoxiclav with food and drink:

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7. Taking Co-Amoxiclav with other medicines
Using other medicines
• If you are taking allopurinol (used for gout) with Co-Amoxiclav, you may be more likely to have an allergic skin reaction.
• If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-Amoxiclav. When you stop taking Co-Amoxiclav, you should check with your doctor or pharmacist.
• If you are going to have surgery, you should let the surgeon know you are taking Co-Amoxiclav.

8. What to do if you do not feel well while you are taking Co-Amoxiclav
If you get any side effects, talk to your doctor or pharmacist. They may be able to help if you are feeling unwell.

9. Taking Co-Amoxiclav during pregnancy or breast-feeding
If you are pregnant, think you might be pregnant or are breast-feeding, please tell your doctor or pharmacist.

10. How to store Co-Amoxiclav

11. Disposal of unused medicine
Medicines must not be disposed of via wastewater or in general waste.

12. Information about other ingredients
Other ingredients are: Magnesium stearate, crospovidone, sodium starch glycolate, polyvinylpyrrolidone, colour E133, titanium dioxide (E171), polyethylene glycol, hydroxypropyl cellulose, sodium hydrogen carbonate, hydrogenated vegetable oil, sodium alginate, gelatin, polysorbate 80, E463, Povidone K90, croscarmellose sodium, polyethylene glycol 400, sodium hydroxide, sodium metabisulfite, colour E131, sugar, D-xylose, lactose monohydrate, sorbitol, Kathon CG, magnesium stearate, hypromellose, wax esters, sodium metabisulfite, titanium dioxide (E171), polysorbate 80, E463, E133, E142E, E150D, E171, E551, E572, E171, E903, E904, E906, talc, ferric oxide (E172), dihydroxypropyl polysiloxane, saccharin sodium, magnesium stearate, crospovidone, titanium dioxide (E171).

13. How to dispose of the packaging and the special membranes
You should contact your local authority to find out how to dispose of the packaging and the special membranes.

14. How to obtain this leaflet
If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), tell the doctor or nurse that you are taking Co-Amoxiclav. This is because Co-Amoxiclav can affect the results of these kinds of tests.

15. How to report side effects
If you think you are having side effects, please report them to your doctor or pharmacist. They may be able to help if you are feeling unwell. If you think Co-Amoxiclav is making you ill, please report this to the manufacturer of this medicine and the National Reporting Scheme for side effects of medicines (see page 3).

16. Product information and package leaflet version
Version: 2
16 June 2014

Sandoz GmbH, Biochemiestrasse 10,
89399 Ulm, Germany
If you forget to take Co-Amoxiclav
If you forget to take a dose of this medicine, take the forgotten dose as soon as you remember. But do not take the next dose too soon, there must be a minimum of 4 hours between two doses. Do not take a double dose to make up for the forgotten individual dose.

If you stop taking Co-Amoxiclav
Keep taking this medicine until the treatment is finished, even if you feel better. If you stop taking this medicine too soon, the infection may come back. Also, the bacteria may become resistant to the medicine. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible side effects
Like all medicines, Co-Amoxiclav can cause side effects, although not everybody gets them.

If any of the following side effects occur, stop taking Co-amoxiclav and go to the hospital at once:
- Allergic reactions such as:
  - 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.
- Serious skin reactions such as:
  - 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 blistering (exanthematous pustulosis)
  - a skin rash which may blister and looks like a small target (a central dark spot surrounded by a paler area, with a dark ring around the edge – erythema multiforme).
- Inflammation of the large intestine causing watery diarrhoea usually with blood and mucus, stomach pain and fever.
- Inflammation of the protective membrane surrounding the brain (aerotic meningitis).
- Jaundice, caused by increased bilirubin in the blood (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow.

Very common side effects - affect more than 1 in 10 people
- diarrhoea (in adults).

Common side effects - 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 dosages - if affected take Co-Amoxiclav before food
- vomiting (being sick)
- diarrhoea (children).

Uncommon side effects - affect up to 1 in 100 people
- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headaches.

Uncommon side effects that may show up in blood tests:
- increase in some substances (enzymes) produced by the liver.

Rare side effects that may show up in your blood tests (affect up to 1 in 1,000 people)
- 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.
- inflammation of the liver (hepatitis)
- inflammation of tubes in the kidneys
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Co-Amoxiclav or who have kidney problems)
- black tongue which looks hairy.

Other effects that may occur:
- severe reduction in the numbers of white blood cells
- a low number of red blood cells (haematolytic anaemia)
- crystals in the urine.

Further information
What Co-Amoxiclav contains:
The active substances are amoxicillin and clavulanic acid.
- 250 mg amoxicillin as amoxicillin trihydrate
- 125 mg clavulanic acid as potassium clavulanate

Other ingredients are: Magnesium stearate (E572), povidone, talc, croscarmellose sodium, microcrystalline cellulose, triethyl citrate, ethyl cellulose, sodium lauryl sulphate, cetly alcohol, hyprolucelose, and titanium dioxide (E171).

What Co-Amoxiclav looks like and contents of the pack:
Each tablet is oblong, convex and off white in colour. The tablets are scored on both sides. Co-Amoxiclav 250/125 mg Tablets are supplied in blister packs of 15 or 21 tablets and hospital packs of 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Sandzol GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

The leaflet was last revised in 06/2014.
PL 045200054

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