Package leaflet: Information for the Patient/User

Co-Amoxiclav 1000/200 mg

Powder for Solution for Injection/Infusion
Amoxicillin/Clavulanic Acid

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet

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 component (clavulanic acid) stops this from happening.

Co-amoxiclav is used in adults and children to treat the following infections:
- severe ear, nose and throat infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections
- intra-abdominal infections
- genital organ infections in women

Co-amoxiclav is used in adults and children to prevent infections associated with major surgical procedures.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CO-AMOXICLAV

You should not be given Co- amoxiclav:
- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid or penicillin
- 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

You should not be given Co-amoxiclav if any of the above apply to you.
If you are not sure, talk to your doctor, pharmacist or nurse before having this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you have this medicine:
- if you have glandular fever
- if you are being treated for liver or kidney problems
- if you are not passing water regularly.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before you are given Co-amoxiclav

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
Tell your doctor or nurse if you are using, have recently used or might use 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, 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.

If medicines to help stop blood clots (such as Warfarin) are taken with Co-Amoxiclav then extra blood tests may be needed.

Co-Amoxiclav can affect how Methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Co-amoxiclav may affect how Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Co-Amoxiclav contains sodium and potassium
The sodium content is 62.9mg (2.7 mmol) per vial. The potassium content is 39.3mg (1 mmol) per vial. This should be considered if you are on a controlled sodium or potassium diet or you have kidney problems.

3. HOW CO-AMOXICLAV IS GIVEN

A qualified person, like a doctor or a nurse, will give you this medicine. It will be given as an injection into a vein or by an intravenous infusion (drip).
You will not normally be given Co-amoxiclav for longer than 2 weeks without the doctor reviewing your treatment.
Make sure you drink plenty of fluids while having Co-amoxiclav.

The usual doses are:
Adults and children weighing 40kg and over

Standard dose	1000 mg/200 mg every 8 hours
To stop infections during and after surgery	1000 mg/200 mg before the surgery when you are given your anaesthetic The dose can differ depending on the type of operation you are having. Your doctor may repeat the dose if your surgery takes longer than 1 hour

Children weighing less than 40kg

Children aged 3 months and over	25 mg/5 mg for each kilogram of bodyweight every 8 hours
Children aged less than 3 months or weighing less than 4 kg	25 mg/5 mg for each kilogram of bodyweight every 12 hours.

Patients with kidney and liver problems
- If you have kidney problems you may be given a different dose. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems your doctor will keep a close check on you and you may have more regular liver function tests.

If more Co-Amoxiclav is given to you than recommended
It is unlikely you will be given too much, but if you think you have been

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Co-Amoxiclav 1000/200 mg Powder for Solution for Injection/Infusion

The following information is intended for medical or healthcare professionals only:
Please refer to the Summary of Product Characteristics for further information

Administration

Co-amoxiclav may be administered either by slow intravenous injection over a period of 3 to 4 min directly into a vein or via a drip tube or by infusion over 30 to 40 min. Co-amoxiclav is not suitable for intramuscular administration.

Reconstitution

For Single use only. Discard any unused solution. The reconstitution/dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discolouration prior to administration.
The solution should only be used if the solution is clear and free from particles.
Preparation of solutions for intravenous injection:
Co-amoxiclav injection should be dissolved in 20ml of solvent (usually water for injection). This yields approximately 20.9 ml of solution for single-dose use which should be administered within 20min of reconstitution. A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or a pale straw colour.

Dilution for infusion:
Co-amoxiclav powder should be reconstituted as described above and added to 100 ml of infusion fluid using a minibag or in-line burette without delay. The infusion should be used immediately.
Discard any unused solution.

Dosage

Adults and children ≥40 kg:

For treatment of infections:	1000 mg/ 200 mg every 8 hours
For surgical prophylaxis:	For procedures less than 1 hour in duration, the recommended dose of Co-amoxiclav is 1000 mg/200 mg to 2000 mg/200 mg given at induction of anaesthesia (Doses of 2000 mg/200 mg can be achieved by using an alternative intravenous formulation of Co-amoxiclav). For procedures greater than 1 hour in duration, the recommended dose of Co-amoxiclav is 1000 mg/200 mg to 2000 mg/200 mg given at induction of anaesthesia, with up to 3 doses of 1000 mg/200 mg in 24 hours. Clear clinical signs of infection at operation will require a normal course of intravenous or oral therapy post-operatively.

Children ≤ 40 kg

Recommended doses:
Children aged 3 months and over: 25 mg/5 mg per kg every 8 hours
Children aged less than 3 months or weighing less than 4 kg: 25 mg/5 mg per kg every 12 hours.

Elderly

No dose adjustment necessary.

Renal impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

given too much Co-Amoxiclav, tell your doctor or nurse immediately. Signs may be an upset stomach (feeling sick, being sick or diarrhoea) or convulsions.

If you have any further questions about how this product is given, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

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
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Contact a doctor immediately if you get any of these symptoms. **You must not be given any more Co-amoxiclav.**

Inflammation of large intestine
Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Acute inflammation of the pancreas (acute pancreatitis)
If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

Drug-induced enterocolitis syndrome (DIES):
DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.
Contact your doctor as soon as possible for advice if you get these symptoms.
Common side effects (these may affect up to 1 in 10 people)
- thrush *(candida* - a yeast infection of the vagina, mouth or skin folds)
- diarrhoea

Uncommon side effects (these may affect up to 1 in 100 people)
- skin rash, itching
- raised itchy rash (*hives*)
- feeling sick (nausea), especially when given high doses. If affected you should be given Co-amoxiclav before food
- vomiting
- 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
- swelling and redness along a vein which is extremely tender when touched

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 **Contact a doctor immediately if you get any of these symptoms:**
  - 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*).
  - Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- 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
- convulsions (fits). This usually only happens in people having high doses or with kidney problems.
- rash with blisters arranged in a circle with central crusting or like a string of pearls *(linear IgA disease)*
- inflammation of the membranes that surround the brain and spinal cord *(aseptic meningitis)*.

Side effects that may show up in blood or urine tests:
- extremely low number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine leading to acute kidney injury

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW CO-AMOXICLAV IS STORED

Keep out of the sight and reach of children.

Do not store above 25 °C. After the powder is made into a solution it should be used immediately.

Do not use Co-amoxiclav after the expiry date that is stated on the outer packaging after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-amoxiclav contains
The active ingredients are amoxicillin and clavulanic acid. Each vial contains 1000mg amoxicillin (as amoxicillin sodium) and 200mg clavulanic acid (as clavulanate potassium).
There are no other ingredients.

What Co-amoxiclav looks like and contents of the pack
Co-amoxiclav is a white, or almost white, powder for solution/infusion in a clear glass vial.
Each pack contains 10 vials.

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Antibiotice SA, 1 Valea Lupului, Iasi 707410, Romania

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Adults and children ≥ 40 kg

CrCl: 10-30 ml/min	Initial dose of 1000 mg/200 mg and then 500 mg/100 mg given twice daily
CrCl < 10 ml /min	Initial dose of 1000 mg/200 mg and then 500 mg/100 mg given every 24 hours
Haemodialysis	Initial dose of 1000 mg/200 mg and then followed by 500 mg/100 mg every 24 hours, plus a dose of 500 mg/100 mg at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased)

Children ≤ 40 kg

CrCl: 10-30 ml/min	25 mg/5 mg per kg given every 12 hours
CrCl < 10 ml /min	25 mg/5 mg per kg given every 24 hours
Haemodialysis	25 mg/5 mg per kg given every 24 hours, plus a dose of 12.5 mg/2.5 mg per kg at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased).

Hepatic impairment
Dose with caution and monitor hepatic function at regular intervals.