PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

SZ88015LT05A

Co-amoxiclav 500 mg/100 mg Powder for Solution for Injection/Infusion
Co-amoxiclav 1000 mg/200 mg, powder for solution for injection/infusion

amoxicillin and 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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 have Co-amoxiclav

Do not take Co-amoxiclav:
- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
- 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, pharmacist or nurse before having Co-amoxiclav.

Warnings and precautions
Talk to your doctor, pharmacist or nurse 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 apply to you, talk to your doctor, pharmacist or nurse before taking 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, pharmacist 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), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav then extra blood tests may be needed.
If you are taking Methotrexate (used to treat cancer and severe psoriasis penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

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

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

Driving and using machines
Co-amoxiclav can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

500 mg/100 mg powder for injection or infusion
- Co-amoxiclav, 500 mg/100 mg contains approximately 31.4 mg (1.4 mmol) of sodium. This is equivalent to 1.57 % of the recommended maximum daily dietary intake of sodium for an adult.
- Co-amoxiclav, 500 mg/100 mg contains approximately 19.6 mg (0.5 mmol) of potassium i.e. essentially‘potassium-free’.

1000 mg/200 mg powder for injection or infusion
- Co-amoxiclav, 1000 mg/200 mg contains approximately 62.9 mg (2.7 mmol) of sodium. This is equivalent to 3.145 % of the recommended maximum daily dietary intake of sodium for an adult.
- Co-amoxiclav, 1000 mg/200 mg contains approximately 39.3 mg (1.0 mmol) of potassium. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How Co-amoxiclav is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

The recommended doses are:
Co-amoxiclav 500 mg/100 mg and Co-amoxiclav 1000 mg/200 mg

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 40 kg
- All doses are worked out depending on the child’s bodyweight in kilograms.

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.

How Co-amoxiclav will be given to you
- Co-amoxiclav will be given as an injection into a vein or by intravenous infusion.

Continued on the next page >>

The following information is intended for medical or healthcare professionals only:
Co-amoxiclav 500 mg/100 mg Powder for Solution for Injection/Infusion
Co-amoxiclav 1000 mg/200 mg Powder for Solution for Injection/Infusion

Amoxicillin/Clavulanic Acid

This is an extract from the Summary of Product Characteristics (SmPC) to assist in the administration of Co-amoxiclav. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the SmPC.

ADMINISTRATION
Co-amoxiclav 500 mg/100 mg, Co-amoxiclav 1000 mg/200 mg Powder for Solution for Injection/Infusion 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. Amoxicillin/clavulanic acid is not suitable for intramuscular administration.

INCOMPATIBILITIES WITH DILUENTS AND OTHER MEDICINAL PRODUCTS
Co-amoxiclav 500 mg/100 mg or 1000 mg/200 mg Powder for Solution for Injection/Infusion must not be mixed with amino acid solutions, lipid emulsions, blood and glucose solutions.

Co-amoxiclav 500 mg/100 mg or 1000 mg/200 mg Powder for Solution for Injection/Infusion is less stable in infusions containing dextran or bicarbonate. Reconstituted solution should therefore, not be added to such infusions but may be injected into the drip tubing over a period of three to four minutes.
Because of the inactivation of aminoglycosides by amoxicillin, in-vitro mixing should be avoided.

INSTRUCTIONS FOR USE AND HANDLING
The reconstitution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter prior to administration. The solution should only be used if the solution is clear and free from particles. Any unused solution should be discarded.From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the injection and infusion solutions should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

For single use only.

Co-amoxiclav 500 mg/100 mg
Preparation of intravenous injections:
Vials of 500 mg/100 mg are diluted with 10 ml or up to 20 ml of water for injections.

Vial of	Water for injection	Volume after reconstitution*	Concentration after reconstitution*
500 mg/100 mg 500 mg/100 mg	10 ml 20 ml	10.0 ml 20.2 ml	50.0/10.0 mg/ml 24.8/5.0 mg/ml

* data based on laboratory studies

Continued on the next page >>

- Make sure you drink plenty of fluids while having Co-amoxiclav.
- You will not normally be given Co-amoxiclav for longer than 2 weeks without the doctor reviewing your treatment.

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 given too much Co-amoxiclav, tell your doctor, pharmacist 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 medicine is given, ask your doctor, pharmacist 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. **Stop taking 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 (may affect up to 1 in 10 people)
- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- diarrhoea

Uncommon side effects (may affect up to 1 in 100 people)
- skin rash, itching
- raised itchy rash (hives)
- feeling sick (nausea), especially when taking high doses
- 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 (may affect up to 1 in 1,000 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)
- Crystals in urine leading to acute kidney injury
- 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)
- 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)*.
  - 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))

  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
- Convulsions (in people taking high doses of Co-amoxiclav or who have kidney problems).

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-amoxiclav

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25ºC. Keep the container in the outer carton.
Reconstituted solution:
Chemical and physical in-use stability has been demonstrated for the reconstituted solution for injection for 15 minutes if stored at 25°C and for the reconstituted solution for infusion 60 minutes if stored at 25°C.
From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the injection and infusion solutions should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This measure will help protect the environment.

6. Contents of the pack and other information

What Co-amoxiclav contains
Co-amoxiclav, 500/100 mg
- The active substances are amoxicillin (as the sodium salt) and clavulanic acid (as the potassium salt). Each vial contains 500 mg amoxicillin (as the sodium salt) and 100 mg clavulanic acid (as the potassium salt).

Co-amoxiclav, 1000/200 mg
- The active substances are amoxicillin (as the sodium salt) and clavulanic acid (as the potassium salt). Each vial contains 1000 mg amoxicillin (as the sodium salt) and 200 mg clavulanic acid (as the potassium salt).

There are no other ingredients. However, please see section 2 for further important information about sodium and potassium in Co-amoxiclav.

What Co-amoxiclav looks like and contents of the pack
Co-amoxiclav, 500 mg/100 mg
20 ml vials of colourless glass type II with halogenated butyl rubber stopper and flip-off aluminium cap.
Pack sizes of 1, 5, 10, 20, 30, 50 and 100 vials.
Co-amoxiclav, 1000/200 mg Vials:
20 ml vials of colourless glass type II with halogenated butyl rubber stopper and flip-off aluminium cap;

Pack sizes for 1, 5, 10, 20, 30, 50 and 100 vials
Bottle: 50 ml bottles of colourless glass type II with halogenated butyl rubber stopper and flip-off aluminium cap
Pack sizes for 1, 5 and 10 bottles
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom
Manufacturer: Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria.

This leaflet was last revised in 06/2023.

46272821
SZ88015LT05A

Preparation of intravenous infusions:
The reconstitution of the ready to use solution for infusion has to take place in two steps in order to allow the reconstitution of the necessary volume for solution for infusion:
The vial of 500/100 mg is first reconstituted with one of the compatible intravenous fluids in its vial. This solution has then to be transferred into a suitable infusion bag which should contain the same compatible fluid as used for reconstitution. Controlled and validated aseptic conditions have to be observed.
Vials of 500/100 mg are diluted with 25 ml or up to 50 ml of water for injection or of the following fluids: Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.
If the product is dissolved in water for injection as specified, this solution may be mixed with the following solvents: Water for injection, Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.

Co-amoxiclav, 1000 mg/200 mg
Preparation of intravenous injections:
Vials of 1000/200 mg are diluted with 20 ml of water for injections.

Vial of	Water for injection	Volume after reconstitution*	Concentration after reconstitution*
1000/200mg	20 ml	20,25 ml	49,4/9,9 mg/ml

* data based on laboratory studies
Preparation of intravenous infusions:
Vials of 1000/200 mg are diluted with 20 ml of water for injections or of the following fluids: Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.
The reconstitution of the ready to use solution for infusion has to take place in two steps in order to allow the reconstitution of the necessary volume for solution for infusion:
The vial of 1000/200 mg is first reconstituted with one of the compatible intravenous fluids in its vial. This solution has then to be transferred into a suitable infusion bag which should contain the same compatible fluid as used for reconstitution, with a volume of 50 ml or up to 100 ml. Controlled and validated aseptic conditions have to be observed.

Bottles of 1000/200 mg are diluted with 50 ml of water for injections or of the following fluids: Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.

If the product is dissolved in water for injection as specified, this solution may be mixed with the following solvents: Water for injection, Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.

Solutions for intravenous infusion should be administered in full within 60 minutes of preparation.

After dissolution in water for injection, a transient pink colour may occur; the solution will become clear again rapidly afterwards.

46272821
SZ88015LT05A