



For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Amoxycillin and Potassium Clavulanate for Injection

Clavuxan® Co-amoxiclav

Package leaflet: Information for the user
CO-AMOXICLAV 500MG/100MG AND 1000MG/200MG
POWDER FOR SOLUTION FOR INJECTION OR INFUSION
Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.
• If you have further questions, ask your doctor, pharmacist or nurse

• 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. The name of your medicine is Clavuxan® Co-amoxiclav 500mg/100mg or 1000mg/200mg Powder for Solution for Injection or Infusion. In the rest of this leaflet it is called Clavuxan® Co-amoxiclav Injection.

WHAT IS IN THIS LEAFLET

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1. WHAT CO-AMOXICLAV INJECTION IS AND WHAT IT IS USED FOR

Clavuxan® 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. Clavuxan® 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.

Clavuxan® 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 INJECTION

YOU SHOULD NOT HAVE 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 neck
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not take Clavuxan® Co-amoxiclav if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before having Clavuxan® Co-amoxiclav.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before having 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, pharmacist or nurse before taking Clavuxan® 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 Clavuxan® Co-amoxiclav or a different medicine.

Conditions you need to look out for
Clavuxan® 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 Clavuxan® Co-amoxiclav, to reduce the risk of any problems. See "Conditions you need to look out for" in Section 4.

4. Blood and urine tests
If you are having blood tests (such as red blood cell status checks or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Clavuxan® Co-amoxiclav. This is because Clavuxan® Co-amoxiclav can affect the results of these types of tests.

Other medicines and Clavuxan® 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 Clavuxan® Co-amoxiclav, it may be more likely that you will have an allergic skin reaction. If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Clavuxan® Co-amoxiclav. If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav then extra blood tests may be needed. Clavuxan® Co-amoxiclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Clavuxan® Co-amoxiclav can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works. If you are a transplant patient taking mycophenolate mofetil talk to your doctor.

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, pharmacist or nurse for advice before taking this medicine.

Driving and using machines

Clavuxan® 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.

Clavuxan® Co-amoxiclav contains sodium and potassium:

- 500 mg/100 mg powder for injection or infusion
- Clavuxan® Co-amoxiclav 500 mg/100 mg contains approximately 31.4 mg (1.4 mmol) of sodium. This should be considered if you are on a controlled sodium diet.
- Clavuxan® Co-amoxiclav 500 mg/100 mg contains approximately 19.6 mg (0.5 mmol) of potassium. This should be considered by patients with kidney problems or patients on a controlled potassium diet.
- 1000 mg/200 mg powder for injection or infusion
- Clavuxan® Co-amoxiclav 1000 mg/200 mg contains approximately 62.9 mg (2.7 mmol) of sodium. This should be considered if you are on a controlled sodium diet.
- Clavuxan® Co-amoxiclav 1000 mg/200 mg contains approximately 39.3 mg (1.0 mmol) of potassium. This should be considered by patients with kidney problems or patients on a controlled potassium diet.

3. How Clavuxan® Co-amoxiclav injection 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: 500 mg/100 mg, 1000 mg/200 mg powder for injection or infusion

Adults, and children weighing 40 kg and over

Standard dose 1000 mg/200 mg every 8 hours.
To stop infections during 1000 mg/200 mg before the surgery when you are given your dose. You may also be given and after surgery 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 25 mg/5 mg for each kilogram of body weight every or weighing less than 4 kg 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.

INFORMATION FOR HEALTHCARE PROFESSIONALS

Clavuxan® Co-amoxiclav 500mg/100mg Powder for Solution for Injection or Infusion Co-amoxiclav 1000mg/200mg Powder for Solution for Injection or Infusion

Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Qualitative and Quantitative Composition

500/100mg Injection

Each vial contains 500mg amoxicillin (as sodium salt) and 100mg clavulanic acid (as potassium salt)

1000/200mg Injection

Each vial contains 1000mg amoxicillin (as sodium salt) and 200mg clavulanic acid (as potassium salt).

Refer to Section 6.6 for method of reconstitution

For a full list of excipients, see section 6.1.

Pharmaceutical Form

Powder for solution for injection or infusion.

Co-amoxiclav Powder for Solution for Injection or Infusion is a white or almost white powder.

- Gastrointestinal tract
 - Pelvic cavity
 - Head and neck • Biliary tract surgery.
- Consideration should be given to the official guidance on the appropriate use of antibacterial agents

Posology and Method of Administration

Co-amoxiclav Injection is for intravenous use.

Method of 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. Children aged less than 3 months should be administered Co-amoxiclav by infusion only. Treatment with Co-amoxiclav may be initiated by the use of an intravenous preparation and completed with an appropriate oral presentation as considered appropriate for the individual patient.

Posology

Adults and children 40kg For treatment of infections as indicated in section 4.1: 1000 mg/ 200 mg every 8 hours 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

Renal adjustment is considered necessary.

Dose adjustment

Dose adjustments are based on the maximum recommended level of amoxicillin. No dose adjustment is required in patients

with creatinine clearance (CrCl) greater than 30 ml/min. Adults and children 40kg

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.

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. **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

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 carton. 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 throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT CO-AMOXICLAV CONTAINS

The active substances are amoxicillin (a penicillin) and clavulanic acid. There are no other ingredients

What Co-amoxiclav looks like and contents of the pack

Co-amoxiclav injection is available in two strengths, 500/100mg and 1000/200mg, and is available in packs of 10 glass vials. Co-amoxiclav 500/100mg vials each contain 500mg of amoxicillin (as sodium salt) with 100mg of clavulanic acid (as potassium salt). Co-amoxiclav 1000/200mg vials each contain 1000mg of amoxicillin (as sodium salt) with 200mg of clavulanic acid (as potassium salt).

Manufactured in India by:

TAJ PHARMACEUTICALS LTD.
15-B-108 Atal Gunj, Hyderabad TS 500 012, India.
At: GIDC, Kerala, Bavla, Dist. Ahmedabad - 438225, Gujarat (India).



DISCLAIMER: THE INFORMATION GIVEN BELOW IS FOR THE USE OF MEDICAL SALES REP AND IS NOT FOR DOCTORS.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. This leaflet was last revised in December 2018.

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Not all pack sizes may be marketed.



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