PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-amoxiclav 500mg/100mg & 1000mg/200mg Powder for solution for injection or infusion

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, pharmacist or nurse.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

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In this leaflet:

1. What Co-amoxiclav is and what it is used for
2. Before you are given Co-amoxiclav
3. How Co-amoxiclav is given
4. Possible side effects
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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
- skin and soft tissue infections including dental infections
- urinary tract infections
- bone and joint infections
- intra-abdominal infections
- genital organ infections in women.

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

2. 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 you are given Co-amoxiclav.

Take special care with Co-amoxiclav
Talk to your doctor, pharmacist or nurse before you are given 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 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.

Using other medicines
Please tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines. This includes medicines that can be bought without a prescription and also herbal medicines.

If you are taking allopurinol (for gout) with Co-amoxiclav, it may be more likely that you'll have an allergic skin reaction.

If you are taking probenecid (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 works (methotrexate is a medicine used to treat cancer or rheumatic diseases).

Pregnancy and breast-feeding
Ask your doctor, pharmacist or nurse for advice if you are pregnant or breast-feeding.

Important information about some of the ingredients of Co-amoxiclav
Co-amoxiclav 500 mg/100 mg contains approximately 31.5 mg (1.4 mmol) of sodium and 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.

Co-amoxiclav 500 mg/100 mg contains approximately 19.6 mg (0.5 mmol) of potassium and 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 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 usual doses are:

Adults, and children weighing 40 kg 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
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.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

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 minutes directly into a vein or via a drip tube or by infusion over 30 to 40 minutes. It is not suitable for muscular administration.

Reconstitution with Water for Injections BP:

Co-amoxiclav	Amount of WFI to be added	Final volume
500mg/100mg	10 ml	10.4 ml
1000mg/200mg	20 ml	20.7 ml

A clear, colourless or pale straw coloured solution is produced. Administer by i.v. injection within 20 minutes of reconstitution

Dilution for infusion:
The reconstituted solution should be added without delay to either 50 ml (Co-amoxiclav 500/100mg) or 100ml (Co-amoxiclav 1000/200mg) of infusion fluid using a minibag or in-line burette.

Stability of prepared solutions:
Chemical and physical in-use stability has been demonstrated as shown in the following table:

Infusion Fluid	**Stability (hours)**	
	5° C	**25° C**
Water for injections	8	4
Sodium chloride intravenous infusion 0.9%	8	4
Sodium lactate intravenous infusion (M/6)	-	4
Ringers Solution	-	3
Hartmann's Solution; Ringer-Lactate Solution	-	3
Potassium chloride and Sodium chloride intravenous infusion	-	3

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used, immediately, in-use storage times and conditions are the responsibility of the user.

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.
- Make sure you drink plenty of fluids while being treated with 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 (fits).

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-amoxiclav can cause side effects, although not everybody gets them. The side effects listed below may occur 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 mucous, 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.

Uncommon side effects (these may affect up to 1 in 100 people)
- skin rash, itching
- raised itchy rash (*hives*)
- feeling sick (*nausea*), especially when taking high doses – if affected take 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)
- 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
- 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.

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

Do not store above 25°C.

Keep out of the reach and sight of children.

Do not use Co-amoxiclav after the expiry date which is stated on the carton. 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 contains:
Co-amoxiclav 1000mg/200mg: Each vial contains 1000mg amoxicillin (as amoxicillin sodium) and 200mg clavulanic acid (as clavulanate potassium).
Co-amoxiclav 500mg/100mg: Each vial contains 500mg amoxicillin (as amoxicillin sodium) and 100mg clavulanic acid (as clavulanate potassium).
The vials contain no other ingredients.

What Co-amoxiclav looks like and contents of the pack:
Co-amoxiclav is a white powder in a glass vial.
Each carton contains 1, 5, 10, 20 or 50 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Bowmed Limited
Unit 2, Eastman Way, Stevenage, Herts SG1 4SZ, UK.

Manufacturer:
Istituto Biochimico Italiano Giovanni Lorenzini S.p.A.
Via di Fossignano, 2 - Aprilia (LT), Italy.

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Dosage

Adults and children ≥ 40 kg
For treatment of infections: Co-amoxiclav 1000/200 mg every 8 hours.
For surgical prophylaxis: For procedures less than 1 hour in duration, the recommended dose of Co-amoxiclav is 1000/200mg to 2000/200 mg given at induction of anaesthesia. (Doses of 2000/200mg can be achieved by using an alternative intravenous formulation of Co-amoxiclav). For procedures greater than 1 hour in duration, the recommended dose is 1000/200 mg to 2000/200mg given at induction of anaesthesia, with up to 3 doses of 1000/200 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
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 is considered necessary.

Renal impairment:
Adults and children ≥ 40 kg

CrCl: 10-30 ml/min	Initial dose of 1000/200 mg and then 500/100 mg given twice daily
CrCl < 10 ml /min	Initial dose of 1000/200 mg and then 500/100 mg given every 24 hours
Haemodialysis	Initial dose of 1000/200 mg and then followed by 500/100 mg every 24 hours, plus a dose of 500/100 mg at the end of dialysis.

Children < 40 kg

CrCl: 10 to 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.

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

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

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