PACKAGE LEAFLET

Package leaflet: information for the user

Co-Amoxiclav 1000 mg/200 mg powder for solution for injection/infusion
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.
- 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.

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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 "penicillin's" 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

You should not have Co-amoxiclav

- if you are allergic 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 Co-amoxiclav 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 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 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 tor
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 using or have recently used 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 can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organ) works

Pregnancy and 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 or nurse for advice before taking this medicine.

Co-amoxiclav contains sodium and potassium.
1000 mg/200 mg powder for solution for injection/Infusion

- This medicine contains approximately 62.9 mg (2.7 mmol) of sodium (main component of cooking salt) in each vial. This is equivalent to 3.1 % of the recommended maximum daily dietary intake of sodium for an adult. This medicine 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:

1000 mg/200 mg powder for solution for injection or infusion Adults, and children weighing 40 kg and over

Standard dose	1000 mg/200 mg every 8 hours.
To stop infections after during and 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 1hour.

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 body weight every 8 hours.
Children aged less than 3 months or weighing less than 4 kg	25 mg/5 mg for each kilogram of body weight 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.
- 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

Itis 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 product 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 the 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 1in 10 people)

- thrush (candida - a yeast infection of the vagina, mouth or skin folds)
- diarrhoea

Uncommon side effects (may affect up to 1in 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 (may affect up to 1in 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 protective membrane surrounding the brain (aseptic meningitis)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- 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 rashwith bumps under the skin and blisters (exanthematous 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.
- leading to acute kidney injury.

Reporting of side effects
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

UK Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store Ireland HPRA Pharmacovigilance Website: www.hpra.ie By reporting side affects 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 carton and vial after "EXP". The expiry date refers to the last day of that month.
Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light
Reconstituted solutions for injection should be administered within 15 min after reconstitution.
The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed one hour.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-amoxiclav, contains

Each vial of Co-amoxiclav 1000 mg/200 mg contains amoxicillin 1000 mg (as amoxicillin sodium) and 200 mg clavulanic acid (as potassium clavulanate).

- There are no other ingredients. However, please see section 2 for further important information about sodium and potassium in Co-amoxiclav.
- The doctor, nurse or pharmacist will make up the injection or infusion before use using an appropriate fluid (such as water for injections or an injection/infusion fluid).

What Co-amoxiclav looks like and contents of the pack
Co-amoxiclav is supplied as a clear glass vial of sterile powder for making up as an injection or infusion. The vial is closed with a rubber stopper, foil overseal and flip-top lid. The vial of co-amoxiclav are packed in cartons of 1,5, 10, or 50.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder For UK:
Fresenius Kabi Limited

Cestrian Court, Eastgate Way Manor Park, Runcorn Cheshire,
WA7 1NT
UK

Marketing Authorisation Holder For IE:

Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

Labesfal - Laboratories Almira S.A. Lagedo, Santiago de Besteiros,
3465-157 Santiago de Besteiros Portugal

This medicinal product Is authorised In the Member States of the EEA under the following names

Belgium	Amoxiclav Fresenius Kabi 1000 mg/200 mg poeder voor oplossing voor injectie/infusie
Germany,	Amoxicillin/Clavulansäure Kabi 1000 mg/200 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung
Spain	Amoxicilina/Ácido Clavulánico Kabi 1g/200mg Polvo para solución inyectable y para perfusión
France	Amoxicilline Acide Clavulanique Kabi 1g/200mg ADULTES, poudre pour solution injectable/pour perfusion
Hungary	Amoxicillin/Klavulnsav Kabi
Ireland, UK	Co-Amoxiclav1000 mg/200 mg powder for solution for injection/infusion
Netherlands	Amoxicilline/Clavulaanzur Fresenius Kabi 1000 mg/200 mg poeder voor oplossing voor injectie/infusie
Poland	Amoxicillin/Clavulanic Acid Kabi
Portugal	Amoxicilina/Acido Clavulanico Kabi

This leaflet was last revised in August 2023

The following information is intended for healthcare professionals only

Please refer to the Summary of Product Characteristics for further information

Reconstitution

Preparation of solutions for intravenous injection
Co-amoxiclav should be administered within 15 min of reconstitution.

Co-amoxiclav 1000 mg/200 mg powder for solution for injection/ infusion should be dissolved in 20 ml of water for injection. This yields approximately 20.9 ml of solution for single-dose use (47.8mg/9.6mg/ml). A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or a pale straw colour Co-Amoxiclav should be administered within 15 min of reconstitution.

Preparation of solutions for intravenous infusion
1000 mg/200 mg powder for solution for injection/infusion
Co-amoxiclav 1000 mg/200 mg should be reconstituted as described above for injection. Without delay the reconstituted solution should be added to 100 ml of 9 mg/ml (0.9%) NaCl solution using a mini bag or in-line burette.

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.

Co-amoxiclav vials are not suitable for multi-dose use. 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 discoloured ion prior to administration. The solution should only be used if the solution is clear and free from particles.

Any unused product or waste material should be disposed of in accordance with local requirements

Stability of prepared solutions

Reconstituted solutions for injection should be administered w within 15 min after reconstitution.
The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed one hour.

Co-amoxiclav should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.

If Co-amoxiclav is prescribed concurrently w with an aminoglycoside,
the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

Co-amoxiclav is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions should not therefore be added to such infusions.