PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-Amoxiclav 500mg/100mg or 1000mg/200mg Powder for Solution for Injection and 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 any further questions, ask your doctor or nurse.
• If you get any of the side effects, talk to your doctor 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 contains amoxicillin, which is an antibiotic and clavulanic acid, which prevents amoxicillin being broken down and so makes it work better. Amoxicillin works by killing some types of bacteria that can cause infections. Co-Amoxiclav 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 use Co-Amoxiclav

You should not use Co-Amoxiclav:

- if you are allergic (hypersensitive) 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.

Talk to your doctor or nurse before taking Co Amoxiclav

Warnings and precautions

Talk to your doctor 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 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.
Co-Amoxiclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, prolongation of prothrombin time, 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 'Section 4. Possible Side Effects'**

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 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 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, nurse or for advice before taking this medicine.
You will not be given Co-Amoxiclav unless your doctor thinks it necessary.

Both substances are excreted into breast milk. Consequently, diarrheoa and fungus infection of the mucous membranes are possible in the breast-fed infant. Amoxicillin/ clavulanic acid should only be used during breast-feeding after benefit/ risk assessment by the physician in charge.

Driving and using machines

Co-Amoxiclav may make you feel dizzy, which may affect your ability to drive or operate machinery. Talk to your doctor if you are not sure if you should drive or use machinery.

Co-Amoxiclav contains sodium and potassium.

There is 31.5 mg of sodium per dose for Co-Amoxiclav 500mg/100mg and 63mg of sodium per dose for Co-Amoxiclav 1000mg/200mg. There is 19.6mg potassium per dose for Co- Amoxiclav 500mg/100mg and 39.2mg potassium per dose for Co-Amoxiclav 1000mg/200mg. You should take this into account if you have poor kidneys or are on a low sodium or low potassium diet.

3. How Co-Amoxiclav is given

Your doctor or nurse will ensure that you are given this medicine as prescribed by your doctor. The dose you are prescribed will depend on the type and severity of your infection. Your doctor will tell you how long your treatment with Co-Amoxiclav will last.
Co-Amoxiclav Injection is injected or infused directly into a vein.

The recommended dose is:
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 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.

- 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
It is unlikely you will be given too much, but if you think you have been 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.

If you miss a dose of Co-Amoxiclav
If you think that you may have missed a dose of Co-Amoxiclav talk to your doctor or nurse. You should not have a double dose to make up for a forgotten dose.

If you stop having Co-Amoxiclav
Your doctor may decide to stop treatment into a vein and ask you to continue treatment with Co- Amoxiclav tablets. There will be a different dose and information leaflet supplied with the tablets. Make sure that you read this carefully. It is important that you keep taking Co-Amoxiclav tablets until the prescribed course is finished. Do not stop taking the tablets just because you feel better. If you stop too soon, the infection may start up again.
If you still feel unwell at the end of your prescribed course of treatment, tell your doctor or nurse.
If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects although not everybody gets them.
STOP Co-Amoxiclav straight away and contact your doctor immediately if you experience:

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

- Aseptic meningitis
- 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 and red blood cells (*haemolytic anaemia*)
- low number of red blood cells (*haemolytic anaemia*)crystals in urine.

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: 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
- Increase of some substances (enzymes) produced by the liver

Rare side effects: 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)*
- swelling and redness along a vein which is extreme
- Low number of cells involved in blood clotting
- Low number of white blood cells

Not known: frequency cannot be estimated from the available data
- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- 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*)
- wide spread 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))

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-Amoxiclav

You will not be asked to store your medicine. It will be brought to you ready to be administered straight away. Your doctor or nurse should ensure that Co-Amoxiclav is stored out of the reach and sight of children. It will be stored below 25°C. Your doctor or nurse will ensure that you do not receive Co-Amoxiclav after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Your doctor, nurse, or pharmacist will 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 substances are amoxicillin 500mg or 1000 mg (as amoxicillin sodium) and clavulanic acid 100mg or 200 mg (as potassium clavulanate).
• There are no other ingredients.

What Co-Amoxiclav looks like and contents of the pack
Co-amoxiclav comes in clear glass vials sealed with a rubber stopper and aluminium flip-off cap. Available in packs of 10 vials.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Fannin Ltd,
Fannin House, South County Business Park, Leopardstown, Dublin 18
Manufacturer: Laboratorio Reig Jofre SA
C/Jarma 111, Poligono Industrial
45007 Toledo,
Spain

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Information for Healthcare Professionals
Instructions for use and handling
To reconstitute, Co-Amoxiclav 500mg/100mg dissolve in 10ml Water for injections Ph.Eur. (Final volume 10.5ml).
Co-Amoxiclav 1000mg/200mg dissolve in 20ml Water for Injections Ph.Eur. (Final volume 20.9ml)

Co-Amoxiclav should be given by slow intravenous injection over a period of 3-4 minutes. It may be injected directly into a vein or via a drip tube containing a compatible fluid.
Co-Amoxiclav may be given by short intravenous infusion in Water for

Injections Ph.Eur. After reconstitution in Water for Injections, the contents of the vial should be added immediately to 50ml of infusion fluid if using Co-Amoxiclav 500mg/100mg, or to 100ml of infusion fluid if using Co-Amoxiclav 1000mg/200mg

Co-Amoxiclav is not stable in infusions containing glucose, dextran or bicarbonate.
For single use only. Any residual antibiotic solution should be discarded.