PACKAGE LEAFLET: INFORMATION FOR THE USER

CO-AMOXICLAV TEVA 500 mg/100 mg POWDER FOR SOLUTION FOR INJECTION/INFUSION
CO-AMOXICLAV TEVA 1000 mg/200 mg POWDER FOR SOLUTION FOR INJECTION/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, 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.

What is in this leaflet

1. What Co-Amoxiclav TEVA 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 are given Co-Amoxiclav TEVA

Do not use Co-Amoxiclav TEVA
- 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 use Co-Amoxiclav TEVA if any of the above apply to you.** If you are not sure, talk to your doctor, pharmacist or nurse before having this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Co-Amoxiclav TEVA:

- if you have glandular fever
- if you are being treated for liver or kidney problems
- if you 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 using 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 using 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 using Co-Amoxiclav. This is because Co-Amoxiclav can affect the results of these types of tests.

Other medicines and Co-Amoxiclav TEVA
Tell your doctor, pharmacist or nurse if you are taking/using, have recently taken/used or might take/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 will have an allergic skin reaction.

- If medicines to help stop blood clots (such as warfarin) are taken with Co-Amoxiclav then extra blood tests may be needed.

- Methotrexate (used to treat cancer and severe psoriasis), penicillins may reduce the excretion of methotrexate causing a potential increase in side effects.

- Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

- 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 or pharmacist 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.

Co-Amoxiclav TEVA contains sodium and potassium
<u>500/100 mg Powder:</u>

- This medicine contains 1.7 mmol sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.96 % of the recommended maximum daily dietary intake of sodium for an adult.

1000/200 mg Powder:

- This medicine contains 3.4 mmol sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.91 % of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 1 mmol potassium per vial. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How Co-Amoxiclav TEVA 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/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.

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 TEVA 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 TEVA 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 on the use of this medicine, 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 throat (*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 using 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.

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.
➔ **Contact your doctor as soon as possible** for advice if you get these symptoms.

Drug-induced enterocolitis syndrome (DIES)
DIES has been reported mainly in children receiving amoxicillin/clavanulate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). 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.

Inflammation of the brain lining
Symptoms could include stiff neck, headache, feeling or being sick, fever or feeling disorientated.
➔ **Contact your doctor as soon as possible** for advice if you get these symptoms.

Common (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

➔ if affected use 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 (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.

Not known (frequency cannot be estimated from the available data)
- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the membranes that surround the brain and spinal cord (*aseptic meningitis*) (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*)
    - 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)*).
    - rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*)

➔ **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).

Not known 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 possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Co-Amoxiclav TEVA

Co-Amoxiclav TEVA is for use in hospital only and the expiry date and storage instructions stated on the label are for the doctor, pharmacist or nurse's information. The doctor, pharmacist or nurse will make up your medicine. It should be used within 15 minutes of reconstitution.

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Store in the original container. Do not transfer to another container.

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 use this medicine if you notice any visible signs of deterioration.

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 TEVA contains

- The active substances are amoxicillin and clavulanic acid.
  - Each vial contains 500 mg amoxicillin (as the sodium salt) and 100 mg clavulanic acid (as the potassium salt). The sodium content of each vial is 1.7 mmol. The potassium content of each vial is 0.5 mmol.
  - Each vial contains 1000 mg amoxicillin (as the sodium salt) and 200 mg clavulanic acid (as the potassium salt). The sodium content of each vial is 3.4 mmol. The potassium content of each vial is 1.0 mmol.
- There are no other ingredients. However, see section 2 for further important information about sodium and potassium in Co-Amoxiclav TEVA
- The doctor, pharmacist or nurse 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 TEVA looks like and contents of the pack

- Co-Amoxiclav TEVA is a white or almost white crystalline powder for solution for injection/infusion.
- The product is available in pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva Pharma B.V., Swensweg 5, 2031GA Haarlem, The Netherlands.

Manufacturer(s)
Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands.
Laboratorio Reig Jofré S.A., C/ Jarama 111 Polígono Industrial, Toledo 45007, Toledo, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

500 mg/100 mg:

Netherlands:	Amoxicilline/Clavulaanzuur 500/100 PCH, poeder voor oplossing voor injectie
Ireland:	Co-Amoxiclav TEVA 500 mg/100 mg Powder for Solution for Injection/Infusion

1000 mg/200 mg:

Netherlands:	Amoxicilline/Clavulaanzuur 1000/200 PCH, poeder voor oplossing voor injectie
Italy:	Amoxicillina/Acido Clavulanico Teva 1,2 g polvere per soluzione iniettabile
Ireland:	Co-Amoxiclav TEVA 1000 mg/200 mg Powder for Solution for Injection/Infusion

This leaflet was last revised in February 2023.

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 TEVA 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 TEVA is not suitable for intramuscular administration.

Reconstitution

Preparation of solutions for intravenous injection

Vial of	Water for injection Ph.Eur	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
1000 mg/200 mg 1000 mg/200 mg	20 ml 50 ml	20.25 ml 50.15 ml	49.4/9.9 mg/ml 19.9/4.0 mg/ml

* data based on laboratory studies

Co-Amoxiclav Teva should be dissolved in the appropriate amount of solvent as mentioned in above table giving a solution for single-dose use which should be administered within 15 min of reconstitution.

A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or of a varying pale yellow/straw colour.

Preparation of solutions for intravenous infusion

For 500 mg/100 mg:
Vials of 500 mg/100 mg are diluted with 10 ml or up to 20 ml of water for injections. 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.

For 1000 mg/200 mg:
Vials of 1000 mg/200 mg are diluted with 50 ml or up to 100 ml of water for injection or the following fluids: Physiological saline, Sodium lactate 167 mmol/l, Ringer's solution, Hartmann's solution.

Solutions for intravenous infusion should be administered in full within 60 min of preparation.
A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or of a varying pale yellow/straw colour.

Stability of prepared solutions
The prepared solutions should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.