

## **Package leaflet: Information for the patient**

### **Co-amoxiclav 250 mg/125 mg film-coated tablets** Amoxicillin/clavulanic acid

**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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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
2. What you need to know before you take Co-amoxiclav
3. How to take Co-amoxiclav
4. Possible side effects
5. How to store Co-amoxiclav
6. Contents of the pack and other information

#### **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:

- sinus infections
- urinary tract and kidney infections
- skin infections
- infections from animal bites
- dental infections

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### **2. What you need to know before you take Co-amoxiclav**

##### **Do not take 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, lips, tongue, throat or neck
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Co-amoxiclav if you:

- have glandular fever
- have 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 pharmacist 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 must look out for while taking Co-amoxiclav**

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.

### **Other medicines and Co-amoxiclav**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 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.
- If you are taking methotrexate (a medicine used to treat cancer or rheumatic diseases), Co-amoxiclav can affect how it works and may cause side effects.
- Co-amoxiclav can affect how mycophenolate mofetil (a medicine used after an organ transplant) 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.

You should only use Co-amoxiclav whilst pregnant if your doctor tells you to. This medicine may be harmful to the baby.

Amoxicillin and clavulanic acid can pass into breast milk. If you breast-feed while taking this medicine, your baby may be more likely to get diarrhoea or an infection. You should only use Co-amoxiclav whilst breast-feeding if your doctor tells you to.

### **Driving and using machines**

Co-Amoxiclav can have side effects such as allergic reactions, dizziness or fits that may make you unfit to drive or use machinery.

Do not drive or use machinery unless you are feeling well.

## **3. How to take Co-amoxiclav**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Use in adults and children weighing 40 kg and over**

The recommended dose is 1 tablet three times a day

**Use in children weighing less than 40 kg:**

Co-Amoxiclav tablets should not be taken by children less than 40 kg.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

**Patients with kidney or liver problems**

If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.

If you have liver problems you may have more frequent blood tests to check how your liver is working.

**How to take Co-amoxiclav**

Swallow the tablets whole with a glass of water. Take with a meal. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

Do not take Co-amoxiclav for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

**If you take more Co-amoxiclav than you should**

If you take too much Co-amoxiclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions (fits). Talk to your doctor as soon as possible. Take the medicine carton to show the doctor.

**If you forget to take Co-amoxiclav**

If you forget to take a dose, take it as soon as you remember. You should then wait 4 hours before taking the next dose.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Co-amoxiclav**

Keep taking your medicine until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

Stop taking Co-amoxiclav, contact a doctor immediately or go to your nearest hospital emergency department if you get any of the following:

Allergic reactions:

**Uncommon** (may affect up to 1 in 100 people)

- Skin rash

**Rare** (may affect up to 1 in 1000 people)

- Skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)

**Not known** (frequency cannot be estimated from available data)

- 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

- a widespread red 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))

**The following serious side effects have also been reported:**

**Very common** (may affect up more than 1 in 10 people)

- Diarrhoea, possibly with blood or mucus, stomach pain or fever

**Rare** (may affect up to 1 in 10,000 people)

- frequent infections causing fever, severe chills, sore throat or mouth ulcers (these may be signs of a low number of white blood cells).
- unexplained bruising or bleeding more easily or for longer than normal (these may be signs of a low number of cells involved in blood clotting).

**Not known** (frequency cannot be estimated from the available data)

- 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
- convulsions (especially if you take high doses of Co-amoxiclav or if you have kidney problems).
- Sensitivity to light, stiff neck, body ache, sore throat, severe headache, flu like symptoms. These may indicate you have a type of meningitis that cannot be passed on to others caused by inflammation of the protective membrane surrounding the brain (*aseptic meningitis*).
- tiredness, headaches, shortness of breath when exercising, dizziness, pale or yellowing of the skin or eyes, these may be signs of a low number of red blood cells (hemolytic anemia).
- pain passing urine, lower back pain or fever. These may be signs of a serious kidney problem (interstitial nephritis)

**Other side effects**

**Common** (may affect up to 1 in 10 people)

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds).
- feeling sick (nausea), especially if you take high doses. If affected, take Co-amoxiclav with food.
- being sick (vomiting).

**Uncommon** (may affect up to 1 in 100 people)

- indigestion.
- dizziness.
- headache.
- increase in some substances (*enzymes*) produced by the liver

**Not Known** (frequency cannot be estimated from the available data)

- other infections that are difficult to treat (over-growth of non-susceptible organisms).
- hyperactivity.
- black tongue which looks hairy.
- crystals in urine (seen as cloudy urine or in a urine test)

**Reporting side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects 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 store tablets above 25°C. Store in the original package in order to protect from moisture. Do not use if the tablets are chipped or damaged.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. 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 trihydrate (corresponding to 250 mg amoxicillin) and potassium clavulanate (corresponding to 125 mg clavulanic acid). The other ingredients are magnesium stearate (E572), talc, povidone, microcrystalline cellulose (E460) and croscarmellose sodium. The tablet coating includes triethyl citrate, ethylcellulose, sodium laurylsulfate, cetyl alcohol, hypromellose, talc and titanium dioxide (E171).

### What Co-amoxiclav looks like and contents of the pack

Your medicine comes as an off-white, capsule shaped film-coated tablet with sides that curve out, marked with ‘AXC375’ on one side and ‘GG’ on the other. The tablets are scored on both sides. Co-amoxiclav is available in blisters of 15, 21, or 100 tablets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Mylan, Potters Bar, Herts, EN6 1TL, United Kingdom

### Manufacturer

Generics [UK] Limited, Station Close, Potters Bar, Herts, EN6 1TL, United Kingdom

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### Other sources of information

Detailed information on this medicine is available on the website of the Medicines and Healthcare products Regulatory Agency (MHRA).

### Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or

pharmacist to explain.

2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.