

## Package Leaflet: Information for the patient

### Co-amoxiclav 500mg/125 mg Film-coated Tablets (amoxicillin and 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 your pharmacist.
- This medicine has been prescribed for you (or for your child) 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 film-coated tablets are and what are they used for
2. What you need to know before you take Co-amoxiclav film-coated tablets
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4. Possible side effects
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#### 1. What Co-amoxiclav film-coated tablets are and what are they 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 film-coated tablets are used in adults and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

#### 2. What you need to know before you take Co-amoxiclav film-coated tablets

##### Do not take Co-amoxiclav film-coated tablets

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Co-amoxiclav film-coated tablets (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 throat
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

**Do not take Co-amoxiclav film-coated tablets if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Co-amoxiclav film-coated tablets.

### **Warnings and precautions**

Talk to your doctor or pharmacist 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 applies to you, talk to your doctor or pharmacist before taking Co-amoxiclav film-coated tablets.

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 film-coated tablets or a different medicine.

### **Conditions you need to look out for**

Co-amoxiclav film-coated tablets 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 film-coated tablets, to reduce the risk of any problems. See 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 film-coated tablets. This is because Co-amoxiclav film-coated tablets can affect the results of these types of tests.

### **Other medicines and Co-amoxiclav film-coated tablets**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used, or might take/use any other medicines. This includes medicines taken without a prescription.

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

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

If medicines to help stop blood clots (such as warfarin) are taken with Co-amoxiclav film-coated tablets 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.

Co-amoxiclav film-coated tablets may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant, or are planning to have a baby, or if you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Co-amoxiclav film-coated tablets can have side effects and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

### **Co-amoxiclav film-coated tablets contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Co-amoxiclav film-coated tablets**

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

### **Adults and children weighing 40 kg and over**

The usual dose is

- 1 tablet three times a day

### **Children weighing less than 40 kg**

Children aged 6 years or less should preferably be treated with amoxicillin/clavulanic acid oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Co-amoxiclav film-coated tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

### **Patients with kidney and 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 film-coated tablets**

- Swallow the tablets whole with a glass of water 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 film-coated tablets for more than two weeks. If you still feel unwell you should go back to see your doctor.

**If you take more Co-amoxiclav film-coated tablets than you should,**

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

**If you forget to take Co-amoxiclav film-coated tablets**

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 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 film-coated tablets**

Keep taking Co-amoxiclav film-coated tablets 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. The side effects below may happen with this medicine.

**Conditions you need to look for**

Allergic reactions:

- 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 taking Co-amoxiclav tablets.**

**Inflammation of 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. 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.

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

- diarrhoea (in adults)

**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 when taking high doses  
→ if affected take Co-amoxiclav film-coated tablets with a meal
- vomiting
- diarrhoea (in children)

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

- skin rash, itching
- raised itchy rash (hives)
- 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.

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*)
- 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
- hyperactivity
- convulsions (in people taking high doses of Amoxicillin/clavulanic acid or who have kidney problems)
- black tongue which looks hairy
- overgrowth of non-susceptible organisms

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 renal injury

**Reporting of 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 film-coated tablets**

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 foil after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.  
Do not store above 25°C.

The tablets should be used within 30 days of opening of the pouch.

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 film-coated tablets contain**

The active substances are amoxicillin and clavulanic acid. Each film-coated tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

The other ingredients are Cellulose microcrystalline, sodium starch glycolate, silica colloidal anhydrous, povidone, Eudragit E100, Magnesium stearate, Hypromellose, Titanium dioxide (E171), Macrogol 400, Talc.

### **What Co-amoxiclav film-coated tablets look like and contents of the pack**

Co-amoxiclav are white to off-white film-coated oval shaped tablets debossed with RX713 on one side and plain on the other side.

Pack sizes of 10, 12, 14, 15, 16, 20, 21, 24, 30, 40 or 50 film-coated tablets packed in PVC/PVdC/Alu blister pack in pouch (Polyester film/Aluminium foil/Polyester film/Polyethylene) with 1g sachet containing desiccant.

Do not eat the desiccant sachet contained inside the pouch.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **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.