

Package leaflet: Information for the patient

Amoxicillin/clavulanic acid Krka 500 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 Amoxicillin/clavulanic acid Krka is and what it is used for
2. What you need to know before you take Amoxicillin/clavulanic acid Krka
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4. Possible side effects
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1. What Amoxicillin/clavulanic acid Krka is and what it is used for

Amoxicillin/clavulanic acid Krka is an antibiotic and works by killing bacteria that cause infections. It contains two different active ingredients 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.

Amoxicillin/clavulanic acid Krka is 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 Amoxicillin/clavulanic acid Krka

Do not take Amoxicillin/clavulanic acid Krka

- 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 (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 Amoxicillin/clavulanic acid Krka if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin/clavulanic acid Krka.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicillin/clavulanic acid Krka 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 pharmacist before taking Amoxicillin/clavulanic acid Krka.

In some cases, your doctor may investigate the type of bacteria that is causing your or your child's infection. Depending on the results, you or your child may be given a different strength of Amoxicillin/clavulanic acid Krka or a different medicine.

Conditions you need to look out for

Amoxicillin/clavulanic acid Krka 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 or your child is taking Amoxicillin/clavulanic acid Krka, to reduce the risk of any problems. See '*Conditions you need to look out for*' in **Section 4**.

Blood and urine tests

If you or your child is 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 or your child is taking Amoxicillin/clavulanic acid Krka. This is because Amoxicillin/clavulanic acid Krka can affect the results of these types of tests.

Other medicines and Amoxicillin/clavulanic acid Krka

Tell your doctor or pharmacist if you or your child is taking, have recently taken or might take any other medicines.

If you are taking allopurinol (used for gout) with Amoxicillin/clavulanic acid Krka, 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 Amoxicillin/clavulanic acid Krka.

If medicines to help stop blood clots (such as warfarin) are taken with Amoxicillin/clavulanic acid Krka then extra blood tests may be needed.

Amoxicillin/clavulanic acid Krka can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Amoxicillin/clavulanic acid Krka may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Amoxicillin/clavulanic acid Krka with food, drink

Take Amoxicillin/clavulanic acid Krka at the start of a meal or slightly before and swallow the tablets whole with a glass of water.

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

Amoxicillin/clavulanic acid Krka can have side effects and the symptoms may make you unfit to drive.

Don't drive or operate machinery unless you are feeling well.

Amoxicillin/clavulanic acid Krka 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 Amoxicillin/clavulanic acid Krka

Always take this medicine exactly as your doctor or pharmacist has told you. 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

Use in children

Children weighing less than 40 kg

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

Ask your doctor or pharmacist for advice when giving Amoxicillin/clavulanic acid Krka 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 or your child has kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you or your child has liver problems you may have more frequent blood tests to check how your liver is working.

How to take Amoxicillin/clavulanic acid Krka

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Amoxicillin/clavulanic acid Krka for more than 2 weeks. If you or your child still feels unwell you should go back to see the doctor.

If you take more Amoxicillin/clavulanic acid Krka than you should

If you take too much Amoxicillin/clavulanic acid Krka, 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 or bottle to show the doctor.

If you forget to take Amoxicillin/clavulanic acid Krka

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

If you stop taking Amoxicillin/clavulanic acid Krka

Keep taking Amoxicillin/clavulanic acid Krka 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.

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 Amoxicillin/clavulanic acid Krka.**

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 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.

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 Amoxicillin/clavulanic acid Krka before food
- 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.

Frequency 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)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- 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)*).

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 Krka or who have kidney problems)
- black tongue which looks hairy

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 Amoxicillin/clavulanic acid Krka

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

Strip and blister

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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 Amoxicillin/clavulanic acid Krka contains

- The active substances are amoxicillin and clavulanic acid.
Each film-coated tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate).
- The other ingredients (excipients) are microcrystalline cellulose (E460), sodium starch glycolate (type A), colloidal anhydrous silica (E551) and magnesium stearate (E470b) in the tablet core and titanium dioxide (E171), hypromellose (E464), propylene glycol (E1520), talc (E553b) and ethylcellulose (E462) in the film coating.
See section 2 "Amoxicillin/clavulanic acid Krka contains sodium".

What Amoxicillin/clavulanic acid Krka looks like and contents of the pack

White coloured capsule shaped film-coated tablet (tablet) debossed with "I 06" on one side and plain on other side, tablet length: 19.40 ± 0.10 mm.

Amoxicillin/clavulanic acid Krka is available in boxes of:

- 10, 12, 14, 16, 20, 21, 24, 30, 100 or 500 film-coated tablets in strips.
- 10, 12, 14, 16, 20, 21, 24, 30, 100 or 500 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Name of the Member State	Name of the medicine
Czech Republic, Denmark, Estonia, Finland, Hungary, Croatia, Lithuania, Latvia, Sweden, Slovak Republic, Slovenia	Betaklav
Austria	Amoxicillin/Clavulansäure Krka
Bulgaria	Бетаклав
Ireland	Amoxicillin/clavulanic acid Krka
Italy	Amoxicillina e acido clavulanico Krka
Poland	Hiconcil combi

This leaflet was last revised in

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. Check with your doctor or pharmacist if you are not sure.
2. Do not take an antibiotic unless it has been prescribed specifically for you and only for the infection it was prescribed.
3. Do not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. Do not give antibiotics prescribed for you to other people.

5. If you have any antibiotic left over when you have taken the course as prescribed you should take the remainder to a pharmacy for appropriate disposal.