

Package leaflet: Information for the patient

Amoxicillin/Clavulanic acid <NAME> 875 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 (or for your child). Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What Amoxicillin/Clavulanic acid <NAME> is and what it is used for
2. What you need to know before you take Amoxicillin/Clavulanic acid <NAME>
3. How to take Amoxicillin/Clavulanic acid <NAME>
4. Possible side effects
5. How to store Amoxicillin/Clavulanic acid <NAME>
6. Contents of the pack and other information

1. What Amoxicillin/Clavulanic acid <NAME> is and what it is used for

Amoxicillin/Clavulanic acid <NAME> 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.

Amoxicillin/Clavulanic acid <NAME> 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 <NAME>

Do not take Amoxicillin/Clavulanic acid <NAME>:

- if you are allergic (hypersensitive) 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 <NAME> if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin/Clavulanic acid <NAME>.

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 apply to you, talk to your doctor or pharmacist before taking Amoxicillin/Clavulanic acid <NAME>.

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 Amoxicillin/Clavulanic acid <NAME> or a different medicine.

Conditions you need to look out for

Amoxicillin/clavulanic acid 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 amoxicilline/clavulanic acid, to reduce the risk of any problems. See '*Conditions you need to look 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 Amoxicillin/Clavulanic acid <NAME>. This is because amoxicillin/clavulanic acid can affect the results of these types of tests.

Other medicines and Amoxicillin/Clavulanic acid <NAME>

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Amoxicillin/Clavulanic acid <NAME>, 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 <NAME>.

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

Amoxicillin/Clavulanic acid <NAME> can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, 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

Amoxicillin/Clavulanic acid <NAME> can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. How to take Amoxicillin/Clavulanic acid <NAME>

Always take this medicine exactly as your doctor 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: 1 tablet two times a day
- Higher dose: 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 Amoxicillin/clavulanic acid <NAME> 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 Amoxicillin/Clavulanic acid <NAME>

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before. Tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablet at the same time.
- 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 <NAME> for more than two weeks. If you still feel unwell you should go back to see the doctor.

If you take more Amoxicillin/Clavulanic acid <NAME> than you should

If you take too much Amoxicillin/Clavulanic acid <NAME>, 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 <NAME>

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 <NAME>

Keep taking Amoxicillin/Clavulanic acid <NAME> 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Amoxicillin/Clavulanic acid <NAME> 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

→ **Contact a doctor immediately** if you get any of these symptoms.
Stop taking Amoxicilline/Clavulanic acid <NAME>.

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.

Very common side effects

These may affect more than 1 in 10 people

- Diarrhoea (in adults)

Common side effects

These 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 <NAME> before food
- Vomiting
 - Diarrhoea (in children)

Uncommon side effects

These 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 side effects

These 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*)
- **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.

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (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*)

➔ **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 <NAME> or who have kidney problems)
- Black tongue which looks hairy
- Stained teeth (in children), usually removed by brushing

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

If you get side effects

➔ **Tell your doctor or pharmacist** if any of the side effects become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

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 national reporting system listed in Appendix V**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amoxicillin/Clavulanic acid <NAME>

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

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 or blister 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 Amoxicillin/Clavulanic acid <NAME> contains:

- The active substances are amoxicillin and clavulanic acid
- Each tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid
- The other excipients are:
Tablet core: Microcrystalline cellulose (E460), crospovidone (E1202), croscarmellose sodium, colloidal anhydrous silica (E551), magnesium stearate (E470b).
Film-coating: Basic butylated methacrylate co polymer, titanium dioxide (E171), talc (E553b), macrogol 6000.

What Amoxicillin/Clavulanic acid <NAME> looks like and contents of the pack

White to off-white oblong film-coated tablet with score line.

OPA/Al/PVC-Al: 4/5/6/10/12/14/15/16/18/20/21/24/30/36/42/48/54/60/66/72/78/84/90/96/100/500 film-coated tablets.

Not all packages or pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer*Marketing Authorization Holder*

[To be completed nationally]

Manufacturer

PenCef Pharma GmbH
Breitenbachstrasse 13
13509 Berlin, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in month YYYY**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 to 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.