

Package leaflet: Information for the user

Amoxicilline/Clavulaanzuur Devatis 500 mg/125 mg filmomhulde tabletten Amoxicilline/Clavulaanzuur Devatis 875 mg/125 mg filmomhulde tabletten

amoxicilline/clavulaanzuur

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) 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 Amoxicilline/Clavulaanzuur Devatis is and what it is used for
2. What you need to know before you take Amoxicilline/Clavulaanzuur Devatis
3. How to take Amoxicilline/Clavulaanzuur Devatis
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1. What Amoxicilline/Clavulaanzuur Devatis is and what it is used for

Amoxicilline/Clavulaanzuur Devatis 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.

Amoxicilline/Clavulaanzuur Devatis 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 Amoxicilline/Clavulaanzuur Devatis

Do not take Amoxicilline/Clavulaanzuur Devatis:

- 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 take Amoxicilline/Clavulaanzuur Devatis if any of the above apply to you.**

If you are not sure, talk to your doctor or pharmacist before taking Amoxicilline/Clavulaanzuur Devatis.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amoxicilline/Clavulaanzuur Devatis 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 Amoxicilline/Clavulaanzuur Devatis.

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 Amoxicilline/Clavulaanzuur Devatis or a different medicine.

Conditions you need to look out for

Amoxicilline/Clavulaanzuur Devatis 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/Clavulaanzuur Devatis, 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 Amoxicilline/Clavulaanzuur Devatis. This is because Amoxicilline/Clavulaanzuur Devatis can affect the results of these types of tests.

Other medicines and Amoxicilline/Clavulaanzuur Devatis

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 Amoxicilline/Clavulaanzuur Devatis, 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 Amoxicilline/Clavulaanzuur Devatis.

If medicines to help stop blood clots (such as warfarin) are taken with Amoxicilline/Clavulaanzuur Devatis then extra blood tests may be needed.

Amoxicilline/Clavulaanzuur Devatis can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Amoxicilline/Clavulaanzuur Devatis may 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

Amoxicilline/Clavulaanzuur Devatis can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Amoxicilline/Clavulaanzuur Devatis contains sodium

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

3. How to take Amoxicilline/Clavulaanzuur Devatis

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

500 mg/125 mg tablets:

The usual dose is:

- 1 tablet three times a day

875 mg/125 mg tablets:

- 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 Amoxicilline/Clavulaanzuur Devatis 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 Amoxicilline/Clavulaanzuur Devatis

- Take with a meal.
- Swallow the tablets whole with a glass of water.
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 Amoxicilline/Clavulaanzuur Devatis for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Amoxicilline/Clavulaanzuur Devatis than you should

If you take too much Amoxicilline/Clavulaanzuur Devatis, 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 Amoxicilline/Clavulaanzuur Devatis

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 Amoxicilline/Clavulaanzuur Devatis

Keep taking Amoxicilline/Clavulaanzuur Devatis 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 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 taking Amoxicilline/Clavulaanzuur Devatis.**

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 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.

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 Amoxicilline/Clavulaanzuur Devatis with a meal

- 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.

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 the 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 Amoxicilline/Clavulaanzuur Devatis 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 the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amoxicilline/Clavulaanzuur Devatis

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.

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

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 Amoxicilline/Clavulaanzuur Devatis contains

- The active substances are amoxicillin and clavulanic acid.
Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.
Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.
- The other ingredients are
Tablet core:
Croscarmellose sodium (E468), Cellulose, microcrystalline (E460), Silica, colloidal, anhydrous (E551), Magnesium stearate (E470b)
- *Film-coating:*
Hypromellose (E464), Titanium dioxide (E171), Macrogol (E1521), Polydextrose (E1200), Copovidone (E1208), Triglycerides, medium-chain (E570)

What Amoxicilline/Clavulaanzuur Devatis looks like and contents of the pack

Amoxicilline/Clavulaanzuur Devatis 500 mg/125 mg film-coated tablets are white to off white, oval-shaped, biconvex film coated tablets, 21.1 mm x 10.3 mm x 6.2 mm, debossed with '500' on one side and 'D V' on the other side.

Amoxicilline/Clavulaanzuur Devatis 875 mg/125 mg film-coated tablets are white to off white, capsule-shaped, biconvex film coated scored tablets, 22.1 mm x 10.5 mm x 7.4 mm, debossed with '875' on one side and a score line in between 'D' and 'V' on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Desiccant laminated Al-Al blister packs with 2, 4, 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 24, 25, 30, 35, 40, 50, 60, 90, 100 and 500 film-coated tablets

Not all pack-sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant Holder and Manufacturer

Devatis GmbH
Spitalstr. 22
79539 Lörrach
Duitsland

In het register ingeschreven onder:

Amoxicilline/Clavulaanzuur Devatis 500 mg/125 mg filmomhulde tabletten: RVG 120970

Amoxicilline/Clavulaanzuur Devatis 875 mg/125 mg filmomhulde tabletten: RVG 120971

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Amoxicilline/Clavulaanzuur Devatis 500 mg/125 mg filmomhulde tabletten
Duitsland	Amoxicillin/Clavulansäure Devatis 500 mg/125 mg Filmtabletten

Nederland	Amoxicilline/Clavulaanzuur Devatis 875 mg/125 mg filmomhulde tabletten
Duitsland	Amoxicillin/Clavulansäure Devatis 875 mg/125 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2023.

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.