

Package leaflet: Information for the user

Amoxicilline/Clavulaanzuur Devatis 250 mg/62,5 mg/5 ml poeder voor orale suspensie
Amoxicilline/Clavulaanzuur Devatis 400 mg/57 mg/5 ml poeder voor orale suspensie

Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for them.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine is usually prescribed for a baby or child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 give Amoxicilline/Clavulaanzuur Devatis
3. How to give Amoxicilline/Clavulaanzuur Devatis
4. Possible side effects
5. How to store Amoxicilline/Clavulaanzuur Devatis
6. Contents of the pack and other information

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 give Amoxicilline/Clavulaanzuur Devatis

Do not give your child Amoxicilline/Clavulaanzuur Devatis :

- if they are allergic to amoxicillin, clavulanic acid, penicillin, benzyl alcohol or any of the other ingredients of this medicine (listed in section 6).
- if they 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 they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→ **Do not give Amoxicilline/Clavulaanzuur Devatis to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Amoxicilline/Clavulaanzuur Devatis .

Warnings and precautions

Talk to your doctor or pharmacist before giving your child Amoxicilline/Clavulaanzuur Devatis if they:

- 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 your child, talk to their doctor or pharmacist before giving Amoxicilline/Clavulaanzuur Devatis .

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child 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 your child is 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 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 they 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 your child is taking, has recently taken or might take any other medicines.

If your child is taking allopurinol (used for gout) with Amoxicilline/Clavulaanzuur Devatis , it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the 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 your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before giving them 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 benzyl alcohol and sodium

Amoxicilline/Clavulaanzuur Devatis contains 0.4 mg benzyl alcohol per 5 ml of suspension.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml of suspension, that is to say essentially “sodium-free”.

3. How to give Amoxicilline/Clavulaanzuur Devatis

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

The recommended dose is

Adults and children weighing 40 kg and over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Children weighing less than 40 kg

All doses are worked out depending on the child’s bodyweight in kilograms.

- Your doctor will advise you how much Amoxicilline/Clavulaanzuur Devatis you should give to your child.
- **Recommended dose:** 20 mg amoxicillin/5 mg clavulanic acid to 60 mg amoxicillin/15 mg clavulanic acid for each kilogram of body weight a day, given in three divided doses.
- The **usual dose** is: 25 mg amoxicillin/3.6 mg clavulainic acid to 45 mg amoxicillin/6.4 mg clavulanic acid for each kilogram of body weight a day, given in two divided doses.
- **Higher dose:** up to 70 mg amoxicillin/10 mg clavulainic acid for each kilogram of body weight a day, given in two divided doses.

The package contains a *dosing syringe* with ml indications. You should use it to give the correct dose to your child.

Instructions on how to use the dosing syringe are to be found at the end of this leaflet.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to check how their liver is working.

How to give Amoxicilline/Clavulaanzuur Devatis

- Always shake the bottle well before each dose
- It should be given with a meal
- Space the doses evenly during the day, at least 4 hours apart. Do not give your child 2 doses in 1 hour.
- Do not give your child Amoxicilline/Clavulaanzuur Devatis for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

Preparation of the suspension

- briefly shake the powder in the closed bottle and check, if all of the powder is at the bottom of the bottle before opening;
- open the child-resistant closure by pressing it down and turning it to the left at the same time;
- carefully and completely remove the membrane and discard it;
- fill the bottle with cold tap water to about 1 cm below the mark on the bottle;
- close the bottle and shake vigorously;
- let the foam sink out, fill up again with cold tap water up to the mark on the bottle and shake again.

The white to creamy white suspension is now ready to be used.

Shake the bottle well before each use and then leave it for little while until the foam that has formed has settled.

After use, close the bottle tightly and clean the dosing syringe by repeatedly filling and emptying it with clear water.

The prepared suspension should not be used if the color differs from that described above.

If you give more Amoxicilline/Clavulaanzuur Devatis than you should

If you give your child too much Amoxicilline/Clavulaanzuur Devatis, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Amoxicilline/Clavulaanzuur Devatis

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stops taking Amoxicilline/Clavulaanzuur Devatis

Keep giving your child Amoxicilline/Clavulaanzuur Devatis until the treatment is finished, even if they feel better. Your child needs 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 your child gets any of these symptoms. **Stop giving Amoxicilline/Clavulaanzuur Devatis to your child.**

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 your child gets 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 give Amoxicilline/Clavulaanzuur Devatis to your child 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 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 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*)
- 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 your child gets 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 child's 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

- stained teeth (in children), usually removed by brushing.

Side effects that may show up in 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 your child gets 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 after “EXP”. The expiry date refers to the last day of that month.

Dry powder

Store in the original package in order to protect from light and moisture. The medicinal product does not require any special temperature storage conditions.

Liquid suspension

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Once made up, the suspension should be used within 7 days.

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 ml of suspension contains amoxicillin trihydrate equivalent to 50 mg amoxicillin and potassium clavulanate equivalent to 12.5 mg clavulanic acid.
5 ml of suspension contain amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg clavulanic acid.
- The other ingredients are silicon dioxide, microcrystalline cellulose, carmellose sodium, sucralose, tri-sodium citrate anhydrous, citric acid anhydrous, silica colloidal anhydrous, mannitol, xanthan gum, vanilla flavour, tutti frutti flavour.
- The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 80 mg amoxicillin and potassium clavulanate equivalent to 11.4 mg clavulanic acid.
5 ml of suspension contain amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg clavulanic acid.
- The other ingredients are silicon dioxide, microcrystalline cellulose, carmellose sodium, sucralose, tri-sodium citrate anhydrous, citric acid anhydrous, silica colloidal anhydrous, mannitol, xanthan gum, vanilla flavour, tutti frutti flavour.

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

Amoxicilline/Clavulaanzuur Devatis is a white to creamy white coloured powder supplied in an amber coloured glass bottle of 125 ml or 200 ml.

Once made up, the bottle contains 100 ml (125 ml bottle) or 150 ml (200 ml bottle) of a white to creamy white liquid mixture called a suspension.

Each pack contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 ml graduation marks and an adaptor for the syringe (polyethylene).

Amoxicilline/Clavulaanzuur Devatis is a white to creamy white coloured powder supplied in an amber coloured glass bottle of 100 ml, 125 ml or 200 ml.

Once made up, the bottle contains 35 ml or 70 ml (100 ml bottle), 100 ml (125 ml bottle) or 140 ml (200 ml bottle) of a white to creamy white liquid mixture called a suspension.

Each pack contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 ml graduation marks and an adaptor for the syringe (polyethylene).

Marketing Authorisation Holder and Manufacturer

Devatis GmbH
Spitalstr. 22
79539 Lörrach
Duitsland

Dit geneesmiddel is in het register ingeschreven onder:

Amoxicilline/Clavulaanzuur Devatis 250 mg/62,5 mg/5 ml poeder voor orale suspensie: RVG 117934

Amoxicilline/Clavulaanzuur Devatis 400 mg/57 mg/5 ml poeder voor orale suspensie: RVG 117935

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

The Netherlands	Amoxicilline/Clavulaanzuur Devatis 250 mg/62,5 mg/5 ml poeder voor orale suspensie
Germany	Amoxicillin/Clavulansäure Devatis 250 mg/5 ml + 62,5 mg/5 ml Pulver zur Herstellung einer Suspension zum Einnehmen
The Netherlands	Amoxicilline/Clavulaanzuur Devatis 400 mg/57 mg/5 ml poeder voor orale suspensie
Germany	Amoxicillin/Clavulansäure Devatis 400 mg/5 ml + 57 mg/5 ml Pulver zur Herstellung einer Suspension zum Einnehmen

This leaflet was last revised in January 2024.

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.

Instructions for using the syringe

A syringe is supplied to administer Amoxicilline/Clavulaanzuur Devatis

The syringe is only for use with Amoxicilline/Clavulaanzuur Devatis and must not be used to administer any other medicines, because the markings are specific to this product. The syringe is supplied with an adaptor which allows it to attach to the bottle.

The dose is indicated on the oral dosing syringe in millilitres (ml). You should give your child the dose recommended by their doctor.

Check cleanliness of syringe before use, rinse with clean water if required.

1. Shake the bottle suspension well before each dose.
2. Remove adaptor from syringe. Hold the bottle firmly and insert the adaptor into the neck of the bottle. The adaptor remains in the bottle as a connecting piece between the bottle and the dosing syringe.
3. Insert the syringe into the adaptor ensuring it is secure.
4. Invert bottle holding the syringe in place and withdraw the required dose as indicated by your doctor.
5. Place bottle upright and remove syringe.
6. To give the dose, carefully put the tip of the syringe into the mouth and slowly push down on the plunger of the syringe.
If more than 5 ml have been prescribed per dose, the dosing syringe has to be filled several times.
7. Rinse syringe thoroughly in clean water. Allow the syringe to dry completely before next use.
8. Replace the bottle cap.
9. Store in a refrigerator and always shake before use. Once made up, the suspension should be used within 7 days.

You can deliver the suspension directly from the dosing syringe into the mouth or you put it on a spoon to swallow. When giving directly into the mouth the child should sit upright. The syringe is best emptied slowly against the inside of the cheek to prevent the child from choking.