

Package leaflet: information for the user
Amoxiclav Aristo 875 mg/125 mg film-coated tablets
amoxicillin
clavulanic acid

Read the entire 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.
- Do you have any questions? Please contact your doctor or pharmacist.
Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms 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.

Contents of this leaflet:

1. What Amoxiclav Aristo is and what it is used for
2. When you should not use this medicine or need to be extra careful
3. How to use this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What Amoxiclav Aristo is and what it is used for?

This medicine is an antibiotic that works by killing the bacteria that cause the infection. It contains a combination of two active substances, namely amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called 'penicillins', which can sometimes be rendered inactive. The other active substance (clavulanic acid) prevents this from happening.

This medicine 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
- Infections of bones and joints

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to amoxicillin, clavulanic acid, penicillin, or any of the ingredients in this medicine.
These ingredients can be found in section 6.
- You have ever had an allergic reaction to any antibiotic, such as a skin rash or swelling of the face or throat.
- You have ever had liver problems or jaundice (yellowing of the skin) after taking an antibiotic.

Do not use this medicine if any of the above apply to you. If you are unsure, you should consult your doctor or pharmacist before taking this medicine.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if you:

- have glandular fever (infectious mononucleosis)
- have liver or kidney problems
- do not urinate regularly.

If you are not sure whether any of the above apply to you, you should speak to your doctor or pharmacist before taking this medicine.

In some cases, your doctor may determine which type of bacteria is causing your infection. Depending on the results, you may be prescribed a different strength of this medicine or another medicine.

Watch for the following signs

This medicine can worsen some existing symptoms or cause serious side effects. This includes allergic reactions, seizures (convulsions), and inflammation of the colon. If you use this medicine, you should watch for these signs to reduce the risk of complications. reduce (see section 4 "Signals to watch out for include:").

Blood and urine tests

If blood is taken to check how your liver is working (liver function tests) or if your urine is tested (for glucose), tell your doctor or nurse that you are using this medicine. It is important that they know this because this medicine can affect the results of such tests.

Are you taking any other medicines?

Are you taking any other medicines besides Amoxiclav Aristo, have you done so recently, or are you going to do so soon? Then tell your doctor or pharmacist.

- If you take allopurinol (used for gout) together with Amoxiclav Aristo, the chance of an allergic skin reaction increases.
- If you take probenecid (used for gout), your doctor may decide to adjust your dosage of Amoxiclav Aristo.
- If you are taking medicines to prevent blood clots (such as warfarin), additional blood tests may be necessary.
- Amoxiclav Aristo can affect the action of methotrexate (used to treat cancer or rheumatic diseases).
- Amoxiclav Aristo can affect the action of mycophenolate mofetil (used to prevent rejection of transplanted organs).

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

This medicine can cause side effects and these may make you unable to drive. Do not drive or operate machines unless you feel well.

Amoxiclav Aristo contains sodium

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

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Adults and children weighing 40 kg or more

- The usual dosage is 1 tablet twice a day.
- A higher dosage is 1 tablet three times a day.

Children weighing less than 40 kg.

- Children under 6 years should preferably be treated with amoxicillin/clavulanic acid oral suspension (in bottle or sachets).
- Ask your doctor or pharmacist for advice if your child weighs less than 40 kg and is prescribed these tablets. The tablets are not suitable for children weighing less than 25 kg.

Patients with liver and kidney problems.

- If you have kidney problems, the dosage may need to be adjusted. Your doctor may choose a different strength or a different medication.
- If you have liver problems, it may be necessary to have your blood tested more frequently to check if your liver is functioning properly.

How is this medication taken?

- Take during a meal.
- Swallow the tablet whole with a glass of water. The tablets can be broken along the score line to make them easier to swallow. You must take both halves of the tablet at the same time.
- Take the doses evenly spaced throughout the day, with at least 4 hours in between. Never take 2 doses within 1 hour.
- Do not use this medication for more than 2 weeks. If you still feel unwell, return to your doctor.

Have you taken too much of this medication?

If you have taken too much of this medication, you may experience stomach problems (such as nausea, vomiting, or diarrhea) or seizures (convulsions). Inform your doctor as soon as possible. Bring the medication packaging (the box or bottle) to show to the doctor.

Have you forgotten to take this medication?

If you forget to take a dose, take it as soon as you remember. Do not take the next dose too early, 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 this medication.

Continue taking this medication until the course is finished, even if you feel better. You need every dose to fight the infection. If some bacteria survive, the infection can resurface.

Do you have any other questions about using this medication? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone will experience them. The side effects listed below may occur with this medicine.

Signs to watch for include

Allergic reactions

- skin rash
- inflammation of a blood vessel (vasculitis), which may appear as red or purple raised spots on the skin, but can also occur in other parts of the body
- fever, joint pain, swollen glands in the neck, armpit, or groin
- swelling, sometimes of the face or throat (angioedema), which can cause breathing difficulties
- fainting
- chest pain against a background of allergic reactions, which may be a complaint of an allergy-induced heart attack (Kounis syndrome)

Contact a doctor immediately if you experience any of these problems. Stop using this medicine immediately.

Inflammation of the colon

Inflammation of the colon, causing watery diarrhea, often accompanied by blood and mucus, stomach pain and/or fever.

Drug-induced enterocolitis syndrome (DIES):

DIES has been mainly reported in children receiving amoxicillin/clavulanate. It is a specific form of an allergic reaction with the main complaint being repeated vomiting (1-4 hours after taking the medicine). Further complaints may include: abdominal pain, feeling sluggish, having little energy and wanting to sleep a lot (lethargy), diarrhea, and low blood pressure.

Acute inflammation of the pancreas (acute pancreatitis)

If you have severe and persistent pain in the stomach area, this may be a sign of acute inflammation of the pancreas.

Contact your doctor immediately for advice if you experience any of these symptoms.

Very common side effects

These occur in more than 1 in 10 users

- Diarrhea (in adults)

Common side effects

These occur in less than 1 in 10 users

- Thrush (candida – a yeast infection in the vagina, mouth, or skin folds)
- Nausea, especially at high doses

If you experience this, take this medicine with a meal

- Vomiting
- Diarrhea (in children)

Uncommon side effects

These occur in less than 1 in 100 users

- Skin rash, itching
- Itchy raised bumps/rash (hives)
- Upset stomach (indigestion)
- Dizziness
- Headache

Uncommon side effects that can be detected through blood tests:

- Increase in some liver-produced typhoid (enzymes)

Rare side effects

These occur in less than 1 in 1000 users

- Skin rash with blistering and redness resembling pinpoints (dark spots in the center surrounded by a lighter ring and a dark outer ring – erythema multiforme)

Contact your doctor immediately if you experience any of these symptoms.

Rare side effects that can be detected through blood tests:

- A low number of blood cells involved in blood clotting
- A low number of white blood cells

Frequency not known

The frequency cannot be determined from the available data.

- Allergic reactions (see above)
- Inflammation of the colon (see above)
- Inflammation of the membranes around the brain and spinal cord (aseptic meningitis)
- Severe skin reactions:
 - A widespread skin rash with blistering and peeling, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome) and a more severe form, which can cause extensive skin peeling (more than 30% of body surface area – toxic epidermal necrolysis)
 - A widespread red skin rash with small, pus-filled blisters (bullous exfoliative dermatitis)
 - A red, scaly skin rash with thickening under the skin and blisters (pustular exanthem)

- Flu-like symptoms with rash, fever, swollen glands, and abnormal blood test results (such as increased white blood cell count (eosinophilia) and liver enzymes) (drug reaction with eosinophilia and systemic symptoms (DRESS))
- A red rash that often occurs on both sides of the buttocks, upper inner thighs, armpits, and neck (Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE))

Contact your doctor immediately if you experience any of these symptoms.

- Rash with blisters in a circular pattern with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the liver (hepatitis) Jaundice, caused by an increase in the blood of bilirubin (a substance produced in the liver) that can make your skin and whites of your eyes appear yellow
- Inflammation of the kidney tubules
- Blood takes longer to clot
- Hyperactivity
- Seizures/convulsions (in people using high doses of this medication or who have kidney problems)
- A black hairy tongue

Side effects that can be detected through blood or urine tests:

- A severe decrease in the number of white blood cells
- A low number of red blood cells (hemolytic anemia)
- Crystals in the urine, leading to acute kidney injury

Reporting side effects

If you experience side effects, contact your doctor or pharmacist.

This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C.

Store in the original package to protect from moisture.

Do not use this medicine after the expiry date. This can be found on the box or blister pack after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substances in this medicine 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 substances in this medicine are:
Tablet core: microcrystalline cellulose (E460), crospovidone type A (E1202), croscarmellose sodium, colloidal anhydrous silica (E551), magnesium stearate (E470b).
Film coating: basic butylated methacrylate copolymer, titanium dioxide (E171), talc (E553b), macrogol 6000.

What does Amoxiclav Aristo look like and how much is in a package?

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

OPA/Al/PVC-Al blister packaging:

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 mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Aristo Pharma GmbH

Walleroder Str. 8 - 10

13435 Berlin

Germany

Manufacturer

PenCef Pharma GmbH

Breitenbachstrasse 13 - 14

13509 Berlin

Germany

Registered under:

RVG 116980, Amoxiclav Aristo 875 mg/125 mg film-coated tablets

This medicine is registered in EEA member states under the following names:

Germany Amoxiclav Aristo 875 mg / 125 mg Filmtabletten

Netherlands Amoxiclav Aristo 875 mg/125 mg film-coated tablets

This leaflet was last approved in July 2025

General advice on the use of antibiotics

Antibiotics are used to treat infections caused by bacteria. They have no effect on infections caused by viruses.

Sometimes a bacterial infection does not respond to a course of antibiotics. One of the most common reasons for this is that the bacteria causing the infection are resistant to the antibiotic being taken. This means they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for a number of reasons. Careful use of antibiotics can help reduce the chance of bacteria becoming resistant to them.

If your doctor prescribes a course of antibiotics, it is intended only to treat your current illness. By following the advice below, you can help prevent the emergence of resistant bacteria, which would result in the antibiotic no longer working.

1. It is very important that you take the antibiotic at the right dose, at the right time, and for the right number of days. Read the instructions on the label and if you do not understand anything, you should ask your doctor or pharmacist for an explanation.
2. You should only take an antibiotic if it has been specifically prescribed for you, and you should only use it to treat the infection for which it was prescribed.
3. You should not take antibiotics prescribed for other people, even if they had an infection similar to yours.
4. You should not give antibiotics prescribed to you to other people.
5. If there are any antibiotics left after you have taken the course as instructed by your doctor, you should take the remainder to a pharmacy for proper disposal.