

Package leaflet: Information for the user

Augmentin 500 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 further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you (or your child). It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

Contents of this leaflet

1. What is Augmentin and what is it used for?
2. When should you not use this medicine or be extra careful with it?
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 is Augmentin and what is it used for?

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

Augmentin 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 other ingredients in this medicine. You can find these ingredients in section 6.
- you have ever had a severe allergic reaction to any (other) antibiotic. This may have included a skin rash or swelling of the face or throat.
- you have ever had liver problems or jaundice (yellowing of the skin) after using an antibiotic.

Do not use Augmentin if any of the above situations apply to you. If you are not sure, consult your doctor or pharmacist before using Augmentin.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you suffer from glandular fever (infectious mononucleosis)
- if you are being treated for liver or kidney problems
- if you cannot urinate regularly

If you are not sure whether any of the above situations apply to you, consult your doctor or pharmacist before using Augmentin.

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 Augmentin or another medicine.

Watch for the following signs

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

Blood and urine tests

If blood is taken (for example, to check your red blood cells or 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 Augmentin. It is important that they know this because Augmentin can affect the results of such tests.

Are you using any other medications?

Are you using any other medications besides Augmentin, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist.

If you are using allopurinol (a medicine for gout) together with Augmentin, you are more likely to have an allergic skin reaction.

If you are using probenecid (a medicine for gout), your doctor may decide to adjust the dosage of Augmentin.

If you are using medications to prevent blood clots (anticoagulants, such as warfarin) together with Augmentin, it may be necessary for your blood to be monitored more closely.

Augmentin can affect the action of methotrexate (a medicine used to treat cancer or rheumatic diseases).

Augmentin can affect the action of mycophenolate mofetil (a medicine used to prevent the 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

Augmentin can cause side effects and these may affect your ability to drive.

Do not drive or operate machines unless you feel well.

Augmentin contains sodium

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

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Adults and children weighing 40 kg or more

- the recommended dosage is one tablet three times a day

Children weighing less than 40 kg

Children up to 6 years old should preferably be treated with a suspension (in bottle or sachets) containing amoxicillin and clavulanic acid.

Ask your doctor or pharmacist for advice if your child weighs less than 40 kg and is prescribed these Augmentin tablets. The tablets are not suitable for children who weigh 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 for your blood to be tested more frequently to check if your liver is functioning properly

How is Augmentin 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 Augmentin for more than 2 weeks. If you still feel unwell, return to your doctor

Have you used too much of this medicine?

If you have taken too much Augmentin, you may experience stomach problems (such as nausea, vomiting, or diarrhea) or seizures (convulsions). Contact your doctor immediately. Take the medicine packaging (the box) of Augmentin with you to your doctor.

Have you forgotten to use this medicine?

If you forget to take a dose, take it as soon as you remember. Do 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 using this medicine

Continue taking Augmentin until the course is finished, even if you feel better. You need every dose to fight the infection. If some bacteria survive the course, they can cause the infection to return.

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

4. Possible side effects

Like all medicines, this medicine can have side effects. Not everyone experiences them. The side effects listed below may occur with this medicine.

Signs to watch out 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 Augmentin immediately.

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea, often with 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 medication). Other 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 may occur in more than 1 in 10 people

- diarrhea (in adults).

Common side effects

These may occur in up to 1 in 10 people

- thrush (candida - a yeast infection in the vagina, mouth, or skin folds)
- nausea, especially at high doses
- If you experience this, take Augmentin with a meal
- vomiting
- diarrhea (in children).

Uncommon side effects

These may occur in up to 1 in 100 people

- skin rash, itching
- itchy raised bumps/rash (hives)
- indigestion
- dizziness
- headache.

Uncommon side effects that can be detected by blood tests:

- increase in some enzymes produced by the liver (enzyme).

Rare side effects

These may occur in up to 1 in 1,000 people

- skin rash with blistering and redness resembling small targets (a dark spot in the center surrounded by a paler area with a dark outer ring - erythema multiforme)

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

Rare side effects that can be detected by blood tests:

- a low number of blood cells involved in blood clotting
- a low white blood cell count.

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:
 - o a widespread skin rash with blisters and peeling of the skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome) and a more severe form that causes extensive peeling of the skin (more than 30% of the body surface, toxic epidermal necrolysis)

- o a widespread red skin rash with small pus-filled blisters (bullous exfoliative dermatitis)
- o a red, scaly skin rash with bumps under the skin and blisters (exanthematous pustulosis)
- o flu-like symptoms with rash, fever, swollen glands, and abnormal blood test results (such as an increased concentration of white blood cells (eosinophilia) and liver enzymes) (drug reaction with eosinophilia and systemic symptoms (DRESS))
- o a red rash that often occurs on both sides of the buttocks, at the top of the inner thighs, in the 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 Augmentin 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 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.

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

Store below 25°C.

Tablets in the packaging with the desiccant sachet must be used within 30 days after opening.

Store in the original package to protect from moisture.

Do not use the tablets if they are broken or damaged.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed correctly and do 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 and potassium clavulanate, equivalent to 500 mg amoxicillin + 125 mg clavulanic acid.
- The other substances (excipients) in this medicine are:
tablet core: magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose;
tablet coating: titanium dioxide (E171), hypromellose, macrogol 4000, macrogol 6000, and dimethicone.

What does Augmentin look like and what is in a package?

Augmentin 500 mg/125 mg film-coated tablets are white to off-white oval tablets with "AC" embossed on one side and a score line.

They are packaged in:

- blister packs, packed in a cardboard box. Each package contains 4, 10, 12, 14, 16, 20, 24, 30, 100, or 500 tablets.
- blister packs in a sachet, packed in a cardboard box. Also contains a desiccant sachet, do not remove or ingest. Each package contains 14, 20, or 21 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder
GlaxoSmithKline BV
Van Asch van Wijckstraat 55H
3811 LP Amersfoort
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Manufacturer
Glaxo Wellcome Production
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Marketing authorization number

RVG 09840 Augmentin 500 mg/125 mg, film-coated tablets

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Bulgaria, Cyprus, Estonia, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Austria, Poland, Portugal, Romania, Slovakia, Slovenia, Czech Republic, United Kingdom (Northern Ireland)	Augmentin
Germany	Augmentan
Spain	Augmentine

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Advice/medical information

Antibiotics are used to treat bacterial infections. They have no effect on viral infections.

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Sometimes a bacterial infection does not respond to a course of antibiotics. One of the most common causes is because the bacterium causing the infection is resistant to the antibiotic used.

This means that the bacterium survives despite the use of the antibiotic and can even multiply.

Bacteria can become resistant to antibiotics for many reasons. Careful use of antibiotics can reduce the chance of bacteria developing resistance.

When your doctor prescribes you a course of antibiotics, it is only intended to treat your current illness. Paying attention to the advice given below will help prevent the development of resistant bacteria, which would render antibiotics ineffective.

1. It is very important that you take the antibiotic in the correct dosage, with the correct frequency, and for the correct number of days (complete the course). Read the label and the leaflet, and if you do not understand something, consult your doctor or pharmacist.
2. You should only take antibiotics if they are specifically prescribed to you, and you should only take them for the infection for which they are prescribed.
3. You should never use antibiotics that were prescribed to someone else, even if you think you have the same infection.
4. You should never pass on antibiotics prescribed to you to another person.
5. If you have any antibiotics left after completing the course prescribed by your doctor, return them to your pharmacy for disposal.