



Information for the patient

Read this package leaflet carefully before you start taking this medicine.
This medicine has been prescribed for you only, and you must not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
Keep this leaflet, you may need to read it again.

Augmentin 457 mg/5 ml

Amoxicillin trihydrate + Potassium clavulanate Suspension

This information is also intended for the parents and caregivers of small children and younger patients.

What Augmentin is and what it is used for

Augmentin is an antibiotic from the group of penicillins. It consists of two active ingredients: clavulanic acid and amoxicillin. Clavulanic acid controls the major defence or resistance mechanism of numerous bacteria resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This mode of action makes Augmentin effective against numerous bacterial infections. Augmentin may be used only when prescribed by a doctor for the exclusive treatment of the following bacterial infections:

- Nose, throat, tonsil, front/maxillary sinus and ear infections;
- Respiratory tract infections (bronchi and lungs);

What you need to know before you take Augmentin

This medicine was prescribed for you by your doctor for the treatment of the present disorder.
The antibiotic in Augmentin is not effective against all microorganisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it on your own for the treatment of other disorders or other people. Even in case of later occurring new infections you must not use Augmentin without seeing a doctor again.
The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, treatment must not be discontinued prematurely even if you feel better.
Depending on the circumstances, and subject to the doctor's instruction, the treatment may last up to two weeks or longer.

Do not take Augmentin:

Patients who have previously had an allergic reaction to Augmentin, penicillins or cephalosporins should not take Augmentin. An allergy or hypersensitivity manifests itself e.g. in symptoms such as red skin blotches, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. nettle rash) and the mucous membranes, skin rash or a painful tongue.
Augmentin must not be used in case of known or suspected hypersensitivity to one of the other ingredients of the medicine.
Patients with infectious mononucleosis or lymphatic leukaemia must not take Augmentin.

Take special care with Augmentin

This medicine may impair your ability to react, drive and use tools or machines.
If the patient takes an oral contraceptive (the pill) its effectiveness may be reduced while taking antibiotics. This also applies to Augmentin. Your doctor or pharmacist may therefore recommend additional contraceptive measures.
Digestive disorders are possible when taking Augmentin. In case of severe gastrointestinal disorders accompanied by vomiting and diarrhoea, the medicine should be discontinued and the doctor contacted immediately. He/she should also be informed if a rash or pruritus occurs.
In case of diarrhoea, medicines that inhibit bowel peristalsis (bowel motility) must not be taken.
Isolated cases of particularly severe allergic reactions such as (potentially life-threatening) drug rash with eosinophilia and systemic symptoms (DRESS) have been reported after taking Augmentin. Signs of such skin reactions include:
- Influenza-like symptoms with rash and fever;
- Skin rash;
- Swelling of the face or other body parts.

If you detect such symptoms in yourself after taking Augmentin, you must immediately stop the treatment and contact a doctor.

Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric®) are more prone to rashes.

Inform your doctor if you have a renal function disorder.

Inform your doctor if you are taking blood thinners (anticoagulants) concomitantly.

Inform your doctor if you are taking mycophenolate-mofetil-containing medicines that are used after organ transplant as prophylaxis against acute transplant rejection reactions.

You must notify your doctor or pharmacist if you or your child take digoxin-containing medicines.

Special caution is advised in case of insufficient kidney or liver function.

Inform your doctor or pharmacist if you or your child

- are suffering from any other diseases,
- have allergies or
- are taking any other medications (even those you bought yourself) or are applying them externally.

Pregnancy and breast-feeding

The suspensions are intended for children. If you have questions concerning pregnancy and breast-feeding contact your doctor or pharmacist. The use of any type of medicine during pregnancy should be decided with the greatest caution and only after consultation with your doctor or pharmacist. It has been reported in studies on pregnant women with premature rupture of membranes (amniorrhexis) that prophylactic treatment with Augmentin may increase the risk of partially severe intestinal inflammation involving tissue damage in newborn infants.

Breast-feeding

As Augmentin is excreted in small amounts in human milk the possibility of a hypersensitivity reaction (involving symptoms such as reddening of the skin and fever) or diarrhoea should be expected for breastfed infants. Therefore, Augmentin should not be used during breast-feeding or breast-feeding should be discontinued.

How to take Augmentin

Posology/Use

Augmentin should preferably be taken at the start of meals. In this way, optimum efficacy and tolerance are achieved.

Children:

The doctor determines the dose based on the child's body weight and the severity of the infection. Follow the prescribed dosage exactly.

Augmentin 457 mg/5 mL (400/57) suspension is used for certain infections in children aged 2 months and older and must be taken 2 times daily.

Dose recommendations

Unless otherwise prescribed by your doctor the following dose recommendations apply:

Augmentin 457 mg/5 mL:

Augmentin is used to treat certain infections in children starting at the age of 2 months and older.

Tonsillitis and Infections of the lower respiratory tract:

Weight	Approximate age	Dose Augmentin 457 mg/5 mL (400/57) suspension
13 – 15 kg	2 – 3 years	2 times daily 2.5 mL
16 – 18 kg	3 – 5 years	2 times daily 3 mL
19 – 21 kg	5 – 6 years	2 times daily 3.5 mL
22 – 30 kg	6 – 10 years	2 times daily 5 mL
31 – 40 kg	10 – 12 years	2 times daily 7.5 mL

Weight	Approximate age	Dose Augmentin 457 mg/5 mL (400/57) suspension
4 – 6 kg	2 – 6 months	2 times daily 1 mL
7 – 9 kg	6 – 12 months	2 times daily 1.6 mL
10 – 12 kg	1 – 2 years	2 times daily 2 mL
13 – 17 kg	2 – 4 years	2 times daily 5 mL
18 – 26 kg	4 – 8 years	2 times daily 7.5 mL
27 – 35 kg	8 – 10 years	2 times daily 10 mL
36 – 40 kg	10 – 12 years	2 times daily 12.5 mL

An initiated antibiotics therapy should be continued for as long as prescribed by the doctor.
The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, do not discontinue the therapy prematurely.
Do not change the prescribed dosage on your own. If you think that the medicine is too weak or too strong talk to your doctor or pharmacist.
Preparation of the suspensions
Normally, the suspensions are prepared by the pharmacist. If the suspension is not prepared, tap water must be added to the powder as follows:
Augmentin 457 mg/5 mL (400/57) suspension
Shake the bottle with the powder. Carefully fill with tap water (in 2 portions) to the line on the label (62 mL for 70 mL of suspension). Shake the bottle well and let sit for a short time. If necessary, add water again up to the line. This makes a 70 mL ready-for-use suspension. Shake the bottle before each use. 2.5 mL = 228.5 mg active ingredients (200 mg amoxicillin, 28.5 mg clavulanic acid). 5 mL = 457 mg active ingredients (400 mg amoxicillin, 57 mg clavulanic acid).
The suspension should only be prepared immediately before use. If you are not comfortable preparing the suspension yourself, have Augmentin prepared in your pharmacy.

Possible side effects
Gastrointestinal disorders such as stomach discomfort or nausea. Likewise, reactions such as vomiting, retching, loss of appetite, bloating, diarrhoea, soft stools, dyspepsia, belly ache and inflammation of the tongue and oral mucosa may occur.
If Augmentin is taken at the start of meals, gastrointestinal discomfort is less common.
As with all medicines of the penicillin group, allergic reactions with Augmentin are common.
Skin rash, reddening of the skin, pruritus and urticaria (nettle rash) may occur.
Likewise, fungal infections of the skin/mucous membranes may occur.
Dizziness and headaches are uncommon.
Very rarely, hyperactivity, inflammation of the meninges (aseptic meningitis), excitation, anxiety, sleeplessness, confusion, changes in behaviour, giddiness, cramps and sensory disorders may occur.
Rarely, especially after taking the suspension, superficial tooth discolourations have been observed. This discolouration usually disappears again when brushing teeth.
Very rarely, a dark coated tongue, hyperkinesis (excessive movement activity), changes in blood count, prolonged bleeding and pro-thrombin time, inflammation of the liver (hepatitis), inflammation of the kidneys and renal function disorders have been observed.
Very rarely, influenza-like symptoms have been observed such as skin rash, fever, swollen glands and abnormal blood counts (including white blood cells [eosinophilia] and liver enzymes) (drug rash with eosinophilia and systemic systems [DRESS]) (see "What you need to know before you take Augmentin").
When administering amoxicillin at the ages of 0 – 9 months, damage to the tooth enamel (e.g. white striping, discolouration) of the definitive incisors cannot be excluded.
chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
Jaundice has been reported rarely.

Consult your doctor immediately if the following occur:
- Nettle rash, skin rash over large areas of the skin, reddening of the skin;
- Yellowish colour of the skin or white part of the eyes;
- Sudden onset of belly ache or vomiting;
- Severe, bloody or persistent diarrhoea;
- Breathing problems in the form of asthma attacks and hay fever.
Inform your doctor or pharmacist if you notice side effects that are not described here.
To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com.

What else should you be aware of?
For patients with phenylketonuria: the suspensions are sweetened with aspartame.
The dry powder should be stored in unopened containers in a dry place at below 30°C.
Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days.
Do not freeze.

If you notice a discolouration of the Augmentin suspensions, this could indicate that the preparation has changed. If this occurs contact your doctor or pharmacist immediately.
Following completion of treatment, the remaining medicine should be returned to where you obtained it (doctor or pharmacist) for proper disposal.
Do not use this medicine after the expiry date ("EXP") which is stated on the container.
The doctor or the pharmacist can provide additional information. They have the detailed summary of product characteristics.

What Augmentin contains
Augmentin contains the active ingredients amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium salt). Below is the detailed composition of the various commercially available dosage forms for children (where applicable, after preparation):

5 mL suspension contains:	Amoxicillin	Clavulanic acid	Ratio of amoxicillin to clavulanic acid	Ingredients
Augmentin 457 mg/5 mL (400/57)	400 mg	57 mg	7 : 1	Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavours, aspartame.

Contents of the pack and other information
Clear, glass bottles, containing an off-white dry powder.
Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France
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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists.