

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed according to a physician's prescription only

Augmentin ES 600 mg/5 ml

Powder for preparation of oral suspension

Each 5 ml of suspension contains:

600 mg amoxicillin (as trihydrate)

42.9 mg clavulanic acid (as potassium salt)

Each 1 ml of suspension contains:

120 mg amoxicillin (as trihydrate)

8.58 mg clavulanic acid (as potassium salt)

A list of the additional ingredients is detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Augmentin ES 600 mg/5 ml is a medicine for treatment of middle ear infections caused by drug-sensitive bacteria in children from the age of 3 months and weighing less than 40 kg.

Augmentin is an antibiotic that 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" whose action can sometimes be stopped (become inactive). The other active component (clavulanic acid) prevents this from happening.

Therapeutic group

Amoxicillin: Penicillin antibiotic group

Clavulanic acid: Beta-lactamase enzyme inhibitors

2. BEFORE USING THE MEDICINE

Do not give your child Augmentin if:

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

→ **Do not give Augmentin to your child if any of the above apply to your child.** If you are not sure, talk to their physician or pharmacist before giving Augmentin.

Special warnings regarding use of the medicine

Before giving your child Augmentin, check with their physician or pharmacist if:

- they have glandular fever
- they are being treated for liver or kidney problems
- they are not passing water properly.

If you are not sure if any of the above apply to your child, talk to their physician or pharmacist before giving Augmentin.

In some cases, the physician may check the type of bacteria that is causing the infection. Depending on the results, your child may be given a different strength of Augmentin or a different medicine.

Conditions you need to look out for

Augmentin 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 Augmentin, 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 undergoing blood tests (such as red blood cell status tests or liver function tests) or urine tests (for testing glucose levels), let the physician know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Other medicines and Augmentin

If your child is taking, has recently taken, or might take, other medicines including non-prescription medicines, herbal medicines or nutritional supplements, tell the physician or pharmacist.

- if your child is taking allopurinol (used for treatment of gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.
- if your child is taking probenecid (used for treatment of gout), the physician may decide to adjust the dose.
- if your child is taking medicines to help prevent blood clotting (such as warfarin or acenocoumarol) with Augmentin, extra blood tests may be needed.
- Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Augmentin can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breastfeeding and fertility

If your child who is about to take this medicine, is pregnant or breastfeeding,

please tell your physician or pharmacist. Refer to your physician or pharmacist for advice before taking this medicine.

Driving and operating machinery

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

Important information about some of the ingredients of the medicine

- Augmentin contains 2.72 mg aspartame (E951) in each 1 ml. Aspartame is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria', a rare genetic disorder in which phenylalanine accumulates because the body cannot clear it properly.
- Augmentin contains maltodextrin (glucose). If you have been told by the physician that your child has an intolerance to certain sugars, contact their physician before giving this medicinal product.
- This medicine contains less than 23 mg sodium in each 5 ml, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only. The usual dosage is generally:

Adults and children weighing 40 kg or over

- This suspension is not intended for adults and children weighing 40 kg and over. Ask your physician or pharmacist for advice.

Children weighing less than 40 kg

All doses are calculated on the basis of the child's body weight in kilograms.

- Your physician will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring spoon. You should use this to give the correct dose to your baby or child.

Augmentin is not intended for children aged less than 3 months.

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 their physician.
- If your child has liver problems, they may need more frequent blood tests to check their liver function.

Do not exceed the recommended dose

Opening instructions: To remove the cap, press down and twist to the left (turning counter-clockwise) at the same time.

Closing instructions: Close the bottle tightly with the cap, twisting to the right (turning clockwise) until fully closed.

How to give Augmentin

- Always shake the bottle well before each dose
- Give with a meal
- Space the doses evenly throughout the day, at least 4 hours apart. Do not give 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell, refer to a physician again.

If you accidentally have given a higher dosage

If you accidentally have given your child too much Augmentin, the signs might include stomach discomfort (nausea, vomiting or diarrhoea) or convulsions. Refer to their physician as soon as possible. Take the medicine package to show the physician.

If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to give Augmentin

If you forgot to give your child a dose, give it as soon as you remember. Afterwards, do not give your child the next dose too soon, rather, wait about 4 hours before giving the next dose. Do not give two doses within less than 4 hours. Do not give a double dose to make up for a forgotten dose.

Persist with the treatment as recommended by the physician.

If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Each dose is important for your child in order to help fight the infection. If some bacteria survive they can cause the infection to come back.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Augmentin ES 600 mg/5 ml may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. Your child may not suffer from any of them. The side effects detailed below may occur 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 physician immediately** if your child experiences any of these symptoms. **Stop giving Augmentin.**

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhoea usually accompanied by blood and mucus, stomach pain and/or fever.

Drug-induced enterocolitis (inflammation of the intestine) syndrome (DIES)

DIES has been reported mainly in children receiving amoxicillin/clavulanic acid. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

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.

- If your child experiences these symptoms, **contact their physician as soon as possible** for advice.

Side effects according to their frequency:

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 fungal infection of the vagina, mouth or skin folds)
 - nausea, especially when taking high doses
- if nausea occurs, take Augmentin 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 liver enzymes.

Rare side effects

These may affect **up to 1 in 1,000** people:

- skin rash, which may include blisters (which looks like 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 physician 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.

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Drug-induced enterocolitis (inflammation of the intestine) syndrome (DIES) (see above)
- Acute inflammation of the pancreas (acute pancreatitis) (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 (*exanthematous pustulosis*)
 - flu-like symptoms with rash, fever, swollen glands and abnormal blood test results (including an increase in the amount of 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 physician immediately if your child experiences any of these symptoms.**

- inflammation of the liver (*hepatitis*)
- jaundice, caused by an increase of bilirubin (a substance produced in the liver) in the blood which may cause yellowing of the skin and whites of the eyes
- inflammation of tubes in the kidney
- longer blood clotting time
- hyperactivity
- convulsions (in people taking high doses of Augmentin 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 anemia*)

- crystals in urine leading to acute kidney injury.

If a side effect occurs, if one of the side effects worsens, or if your child suffers from a side effect that has not been mentioned in this leaflet, consult with the physician

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Dry powder:

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

Liquid suspension:

- Store in a refrigerator (between 2°C to 8°C). Do not freeze.
- After preparation, use the suspension within 10 days.
- Do not discard medicines via wastewater or household waste. Consult the pharmacist regarding how to discard medicines that are not in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

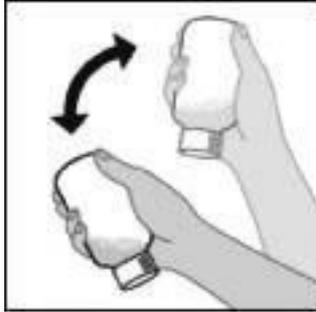
- In addition to the active ingredients the medicine also contains:
Silicon dioxide, colloidal anhydrous silica, carboxymethyl cellulose sodium, artificial strawberry cream flavour (including maltodextrine), aspartame (E951) and xanthan gum.
See also ‘Important information about some of the ingredients of the medicine’, in section 2.
- What the medicine looks like and the content of the package:
Child-resistant bottle packaging.
Augmentin ES 600 mg/5 ml suspension is an off-white powder supplied in a clear glass bottle. After preparation, the bottle contains 100 ml of an off-white liquid mixture called a suspension.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome Production, Mayenne, France.
SmithKline Beecham Pharmaceuticals, Worthing, UK.
- Revised in July 2023 according to MOH guidelines.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 145-87-33332.
- Trade marks are owned by or licensed to the GSK group of companies.
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Instructions for preparation (reconstitution):

Remove the bottle cap. Check that the foil-backed seal is intact before using. Replace the bottle cap.

1. Shake bottle to loosen the powder.



2. Remove the bottle cap.



3. Peel back the foil-backed seal to remove it.



4. To prepare 100 ml suspension, add 90 ml of water. Replace the bottle cap, invert and shake well.