
PATIENT LEAFLET (PL)

AUGMENTIN ES-600

Amoxicillin trihydrate - Potassium clavulanate

Read all of this leaflet carefully before you start taking/giving this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for your child, and you should not pass it on to others. It may harm them, even if their symptoms are the same as your child's.

Formulation and strength

AUGMENTIN ES-600 is usually prescribed for children aged 3 months and older.

AUGMENTIN ES-600 is supplied to you as an off-white to tan coloured, strawberry flavoured, liquid suspension for swallowing.

Amoxicillin content (mg)/clavulanic acid content (mg): 600 mg/ 42.9 mg per 5 ml.

Excipients requiring special warnings

AUGMENTIN ES-600 suspension contains aspartame, which is a source of phenylalanine. This is important if your child has a condition called phenylketonuria (PKU), and you must tell your doctor if they have this condition.

1. WHAT AUGMENTIN ES-600 IS AND WHAT IT IS USED FOR

AUGMENTIN ES-600 is an antibiotic which contains two active ingredients. One of these is a penicillin called amoxicillin (present as amoxicillin trihydrate) and the other is clavulanic acid (present as potassium clavulanate).

AUGMENTIN ES-600 is used to treat children with infections caused by bacteria.

2. BEFORE YOU GIVE AUGMENTIN ES-600

Do not use this medicine if:

- Your child is allergic to amoxicillin or beta-lactam antibiotics (such as penicillins and cephalosporins) or any of the other ingredients of *AUGMENTIN ES-600*. If they have had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before you give *AUGMENTIN ES-600*.
- Your child has ever had jaundice (yellowing of the skin and/or eyes) or liver disease while taking *AUGMENTIN ES-600*.

Take special care and get advice from your doctor if:

- Your child develops signs of an allergic reaction (such as a skin rash or repetitive vomiting within 1 to 4 hours of *AUGMENTIN ES* administration), while taking *AUGMENTIN ES-600*. Do not give any more suspension and tell the doctor at once.
- Your child has glandular fever (mononucleosis) and they are prescribed *AUGMENTIN ES-600*. Please tell the doctor before you give the medicine.
- Your child has liver or kidney problems. The dosage may need to be reduced or they may need to be given a different medicine.
- Your child suffers from a condition called phenylketonuria (PKU). This is because *AUGMENTIN ES-600* contains aspartame.

If your child is taking a contraceptive pill, could be pregnant, or is breast-feeding a baby, you should talk to the doctor before using *AUGMENTIN ES-600*.

Interactions

Some medicines may cause unwanted effects if they are taken at the same time as *AUGMENTIN ES-600*. Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines or supplements, even those that can be bought without a prescription.

It is particularly important that the doctor knows if your child is taking the following medicines:

- allopurinol
- probenecid.
- anticoagulants (used to prevent blood clots) such as warfarin
- mycophenolate mofetil.
- methotrexate (used to treat conditions such as cancer and severe psoriasis).

3. HOW TO USE AUGMENTIN ES-600

You must follow the doctor's advice and use the medicine as instructed. The doctor will decide how much medicine you need to give each day, and how many days you should give it for.

If there is anything you do not understand, please ask your doctor or pharmacist.

It is better to give *AUGMENTIN ES-600* at the same time as a meal, but *AUGMENTIN ES-600* still works if it is given without food.

Make sure the whole dose is swallowed every time.

If you are giving *AUGMENTIN ES-600* to a child up to 2 years old, the dose can be diluted to half-strength using water immediately before you give it. Do not store diluted medicine.

ONCE YOU HAVE STARTED GIVING AUGMENTIN ES-600

Keep giving the medicine until the complete course has been finished. Do not stop when your child feels better.

If your child has taken more AUGMENTIN ES-600 than they should:

Give plenty of water to drink and contact a doctor. Show the doctor the pack of *AUGMENTIN ES-600*.

If you forget to give a dose of AUGMENTIN ES-600:

Give it as soon as you remember, then carry on as before, but do not give two doses within an hour of each other.

4. POSSIBLE SIDE EFFECTS

Like all medicines, *AUGMENTIN ES-600* can cause side effects, but not everybody gets them.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking *AUGMENTIN ES-600*. Signs include:

- raised, itchy rash (*hives*)
- 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 mouth (*angioedema*), which may cause difficulty in swallowing or breathing
- collapse.
- chest pain which can be a sign of a potentially serious allergic reaction called *Kounis syndrome*.
- repetitive vomiting (1 to 4 hours after *AUGMENTIN ES-600* administration), stomach pain, abnormal drowsiness, diarrhoea and low blood pressure which can be a sign of a serious allergic reaction called *drug-induced enterocolitis syndrome*.

→ Get medical help immediately if your child gets any of these symptoms. **Stop giving your child *AUGMENTIN ES-600*.**

Serious skin reactions

These are rare in people taking *AUGMENTIN ES-600*. Signs include:

- 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*).

These are very rare in people taking *AUGMENTIN ES-600*. Signs include:

- 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 blisters and peeling skin on much of the body surface (*toxic epidermal necrolysis*)
- a widespread, red, skin rash with small blisters containing pus (*exanthemous pustulosis*)
- a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including white blood cells (*eosinophilia*) and liver enzymes) (*Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)*).

- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (*Symmetrical Drug-related Intertriginous and Flexural Exanthema (SDRIFE)*).
- **Get medical help immediately** if your child gets any of these symptoms. **Stop giving your child *AUGMENTIN ES-600*.**

Serious liver problems

On rare occasions, medicines like *AUGMENTIN ES-600* can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

- Tell your doctor as soon as possible if your child gets any of these symptoms.

Severe diarrhoea (*Pseudomembranous colitis*)

On rare occasions, medicines like *AUGMENTIN ES* can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever.

- Tell your doctor as soon as possible if your child gets any of these symptoms.

Common side effects

These may affect **up to 1 in 10** people:

- thrush (fungal infection caused by *Candida* in the vagina, mouth or skin folds)
- feeling sick (*nausea*)
- vomiting
- diarrhoea

Uncommon side effects

These may affect **up to 1 in 100** people:

- dizziness
- headache
- indigestion
- skin rash
- itching
- itchy, bumpy rash (*hives*)

Uncommon side effects that may show up in blood tests are:

- increase in some substances (enzymes) produced by the liver

Rare side effects

These may affect **up to 1 in 1,000** 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*) (See ‘*serious skin reactions*’ earlier in Section 4)

Rare side effects that may show up in blood tests are:

- decrease in the number of white blood cells (*leucopenia*, including *neutropenia*)
- decrease in the number of cells that help blood to clot (*thrombocytopenia*)

Very rare side effects

These may affect **up to 1 in 10,000** people:

- severe allergic reactions (See also ‘*severe allergic reactions*’ earlier in Section 4)
- serious skin reactions (See also ‘*serious skin reactions*’ earlier in Section 4)
- inflammation of the liver (*hepatitis*) (See also ‘*serious liver problems*’ earlier in Section 4)
- yellowing of the whites of the eyes or skin (*jaundice*) (See also ‘*serious liver problems*’ earlier in Section 4)
- inflammation of the large intestines (See also ‘*severe diarrhoea*’ earlier in Section 4)
- inflammation of the kidney (*nephritis*)
- an increase in the time blood takes to clot
- being unusually active (*hyperactivity*)
- fits (*seizures*)
- black tongue which looks hairy
- inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- stained teeth that can usually be removed by brushing
- rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*)

Very rare side effects that may show up in blood or urine tests are:

- severe decrease in the number of white blood cells (*agranulocytosis*)
- red blood cells destroyed too quickly (*haemolytic anaemia*)

- crystals in urine

→ **Tell your doctor or pharmacist** if any of the side effects listed becomes severe or troublesome for your child, or if your child has any side effects not listed in this leaflet.

5. HOW TO STORE AUGMENTIN ES-600

Store all medicines out of the reach of children, preferably in a locked cupboard.

The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

The medicine should be kept cool in a refrigerator, or the product may lose some of its effect. Do not freeze it. Use the suspension within 10 days.

Return left-over medicine to your pharmacist.

6. FURTHER INFORMATION

WHAT AUGMENTIN ES-600 LOOKS LIKE AND CONTENTS OF THE PACK

AUGMENTIN ES powder for oral suspension, is supplied in clear glass bottles containing dry powder for reconstitution. Bottles may be supplied with either an aluminium screw cap with a ring seal or a plastic child-resistant cap with a removable foil-backed seal on the bottle. Fill-lines are indicated on the bottle label. Bottles may be supplied with a plastic dosing device.

7. INFORMATION FOR HEALTHCARE PROFESSIONALS

For bottles with aluminum screw caps, check the cap seal is intact before using. Alternatively, for bottles with a plastic child-resistant cap, check the foil-backed bottle seal is intact before using.

At time of use, the dry powder should be reconstituted to form an oral suspension, as detailed below:

- Invert and shake bottle to loosen powder.
- Add volume of water (indicated below). Invert and shake well.
- Alternatively, fill the bottle with water to just below the mark on bottle label. Invert and shake well, then top up with water to the mark. Invert and shake again.
- Shake well before taking each dose.

Bottle Size (ml)	Amount of Water Required for Suspension (ml)
50	50
75	70
100	90
150	135

Each 5 ml will contain 600 mg amoxicillin as the trihydrate and 42.9 mg of clavulanate as the potassium salt.

Not all presentations are available in every country.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd
57 Sloane Street
Bryanston, 2021
South Africa

REGISTRATION DETAILS

Botswana: Reg No: BOT0701009 S2

Namibia: Reg No: 08/20.1.2/0095 NS2

Version number: GDS29/IP114

Date of issue: 07 September 2023

Trade marks are owned by or licensed to the GSK group of companies.

© 2023 GSK group of companies or its licensor.