

AUGMENTIN SUSPENSION

Amoxicillin/ Potassium clavulanate (228 mg/5 ml, 457 mg/5 ml)

What is in this leaflet

1. What Augmentin is used for
2. How Augmentin works
3. Before you use Augmentin
4. How to use Augmentin
5. While you are using it
6. Side Effects
7. Storage and Disposal of Augmentin
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Augmentin is used for

Augmentin is an antibiotic used in children to treat infections in different parts of the body caused by bacteria in respiratory tract, urinary tract, skin and soft tissue and dental infections.

How Augmentin works

Augmentin contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin is a penicillin antibiotic. Amoxicillin can sometimes be stopped from working (made inactive). The other active medicine, clavulanic acid, stops this from happening.

Before you use Augmentin

When you must not use it

Do not use this medicine if:

- Your child is allergic (hypersensitive) to amoxicillin, clavulanic acid, other penicillin based antibiotics, or similar antibiotics called cephalosporins
- Your child has ever had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking an antibiotic.
- If you think any of these apply to your child, check

with your doctor before you take Augmentin.

Before you start to use it

Take special care and get advice from your doctor if:

- Your child has ever had an allergic reaction to any other antibiotics or medicines. This might include a skin rash or swelling of the face or neck.
- Your child has glandular fever (mononucleosis)
- Your child is taking medicines, such as warfarin, that are used to prevent blood clots
- Your child has liver problems
- Your child has kidney disease
- Your child is not urinating regularly or not able to drink very much
- Your child has a genetic condition called phenylketonuria

Check with your doctor if you think any of these may apply to your child. Your doctor will decide whether Augmentin is suitable for your child and may need to adjust the dose or give your child a different medicine.

Taking other medicines

Tell your doctor or pharmacist if your child is taking any other medicines, if your child has taken any recently, or if your child starts taking new ones. This includes medicines bought without a prescription. Some medicines may affect how Augmentin works, or make it more likely that your child will have side effects. Augmentin can

also affect how some other medicines work. These include: Probenecid and allopurinol (used to treat gout)

- Anticoagulants (used to prevent blood clots) such as warfarin and acenocoumarol
- Mycophenolate mofetil (used to prevent the rejection of transplanted organs)
- Methotrexate (a medicine used to treat cancer or rheumatic diseases).

Tell your doctor or pharmacist if your child is taking any of these.

How to use Augmentin

How much to use

Always take Augmentin exactly as your doctor or pharmacist has told you to.

Check with your doctor or pharmacist if you're not sure. Your doctor will decide on the correct dosage for your child.

- Shake the bottle well before taking each dose.
- A dosing syringe, spoon or cup may be supplied with the pack, which you can use to measure the dose accurately.
- A dosing syringe should be used to give the correct dose to children below 3 months.

Patients with kidney or liver problems

- If your child has kidney problems, your doctor may give you a different strength or a different medicine.
- If your child has liver problems, you may have more frequent blood tests to check how your child liver is working.

When to use it

Take Augmentin at the start of a meal or slightly before.

How long to use it

It is important that your child takes the full course of Augmentin. Don't stop unless your doctor advises you to – even if your child is feeling better. If your child doesn't complete the full course of treatment, the infection may come back.

Do not take Augmentin for more than 14 days. If your child still feels unwell you should go back to see your doctor.

If you forget to use it

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember. If you're not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

If your child accidentally takes too much Augmentin, it is unlikely to cause any serious problems. The most common side effects of taking too much Augmentin are nausea, vomiting and diarrhoea.

If you're worried, or your child feels unwell:
Ask your doctor or pharmacist for advice.

While you are using it

Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Things you must not do

This medicine has been prescribed for your child, and you should not pass it on to other. It may harm them, even if

their symptoms are the same as your child's.

Things to be careful of

Take special care and get advice from your doctor if:

- Your child develops a skin rash while taking Augmentin
- Do not give any more suspension and tell the doctor at once

Augmentin suspension contains aspartame, which is a source of phenylalanine. If your child has an intolerance to aspartame or has a condition called phenylketonuria (PKU), check with your doctor that Augmentin is right for your child.

Side Effects

Like all medicines, Augmentin can cause side effects, but not everybody gets them.

Augmentin may cause severe allergy and serious skin reactions. Stop using Augmentin and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

Look out for important symptoms

Severe allergic reactions

These are very rare in people taking Augmentin. 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*.
- Drug-induced enterocolitis syndrome (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.

Get medical help immediately if you get any of these symptoms. Stop taking Augmentin.

Serious skin reactions

These are rare in people taking Augmentin. 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. 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 (*exanthematous pustulosis*)
- a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)

- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Get medical help immediately if you get any of these symptoms. Stop taking Augmentin.

Serious liver problems

On rare occasions, medicines like Augmentin can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

Tell your doctor as soon as possible if you get any of these symptoms.

Severe diarrhoea (*Pseudomembranous colitis*)

On rare occasions, medicines like Augmentin 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 you get any of these symptoms.

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

- diarrhoea (in children).

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*)

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
- serious skin reactions
- inflammation of the liver (*hepatitis*)
- yellowing of the whites of the eyes or skin (*jaundice*)
- inflammation of the large intestines
- 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

Not known side effects

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (*linear IgA disease*).
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (*Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)*).

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, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Augmentin

Storage

- Keep out of the sight and reach of children.
- Do not take Augmentin after the expiry date shown on the pack.

- Store in a dry place in the original packaging to protect from moisture. .
- The dry powder should be stored in unopened containers in a dry place at below 30°C.
- Once made up, the suspension should be stored in a refrigerator (2°C to 8°C).
- Do not freeze.
- Dispose of any unused suspension 7 days after first making up.

Disposal

- Don't dispose of medicines in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

What it looks like

Augmentin is dry powder for reconstitution in water, to form a white to tan mixed-fruit flavoured suspension.

Ingredients

Active ingredient(s):
Amoxicillin trihydrate
Potassium clavulanate

Inactive ingredient(s):
Xanthan gum, aspartame, succinic acid, colloidal silica, hydroxypropylmethylcellulose, silicon dioxide and dry flavours (raspberry, orange "1", orange "2" and golden syrup).

MAL number:

Augmentin Suspension
228mg/5ml:
MAL19986950ARZ

Augmentin Suspension
457mg/5ml:
MAL19986951ARZ

Manufacturer

Glaxo Wellcome Production

ZI de la Peyennière, 53100
Mayenne, France

Product Registration Holder

GlaxoSmithKline Pharmaceutical
Sdn. Bhd.
HZ.01, Horizon Penthouse,
1 Powerhouse,
1, Persiaran Bandar Utama,
Bandar Utama,
47800 Petaling Jaya Selangor,
Malaysia

Date of Revision

14/10/2024

Serial Number

NPRA (R1/6)14012025/008