

# AUGMENTIN SUSPENSION (STRAWBERRY)

Amoxicillin trihydrate/ Potassium clavunate (400 mg/ 45 mg per 5 ml)

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## What AUGMENTIN is used for

Augmentin is used to treat children with infections caused by bacteria in respiratory, urinary tract, skin and soft tissue and dental infections.

## How AUGMENTIN works

Augmentin 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).

## Before you use AUGMENTIN

### - When you must not use it

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. 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.
- Your child has ever had jaundice (yellowing of the skin and/or eyes) or liver

disease while taking Augmentin.

### - Before you start to use it

Take special care and get advice from your doctor if:

- Your child develops hypersensitivity reactions to penicillin, cephalosporins. Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms. If you think your child is having an allergic reaction, stop taking the medicine and contact your doctor immediately or go to the nearest hospital.
- Your child has glandular fever (mononucleosis) and they are prescribed Augmentin. 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 contains aspartame.

### - Taking other medicines

Some medicines may cause unwanted effects if they are taken at the same time as Augmentin. 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 (commonly used to treat gout and high uric acid)
- Probenecid (commonly used to treat gout and high uric acid)
- anticoagulants (used to prevent blood clots) such as warfarin
- mycophenolate mofetil
- Augmentin may affect the gut flora

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

## How to use AUGMENTIN

### - How much to use

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. Make sure the whole dose is swallowed every time.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

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

### - If you forget to use it

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Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Give plenty of water to drink and contact a doctor. Show the doctor the pack of Augmentin.

## **While you are using it**

- *Things you must do*

Check with your doctor or pharmacist before giving this medicine to your child and give 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 others. It may harm them, even if their symptoms are the same as your child's.

- *Things to be careful of*

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

If your child get severe diarrhoea tell your doctor or pharmacist immediately.

Augmentin should be avoided in pregnancy, unless considered essential by the physician. Augmentin may be administered

during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no detrimental effects for the infant.

Augmentin 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.

## **Side Effects**

Most patients do not have any problems with Augmentin. However, like all medicines, Augmentin can have side effects, and some people can be allergic to medicines.

If your child has any of the following symptoms after taking Augmentin, stop giving it and tell your doctor immediately, or take them to the accident and emergency department of your nearest hospital.

These are very rare side-effects that happen to less than 1 in 10,000 people taking AUGMENTIN:

- Sudden wheeziness, shortness of breath, or chest tightness
- Swelling of the face, lips, tongue, or other parts of the body
- Convulsions
- Yellowing of the skin and/or eyes, or dark coloured urine. These symptoms may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may not occur until several weeks after the end of treatment and can be severe.
- Blood in the urine which may be associated with a rash, fever, joint pain, or a

reduction in passing water (urination).

- Severe diarrhoea, which may be bloody, or contain mucus, and which may be accompanied by stomach cramps.
- A rash with blisters that may cause the skin to peel, flake, or bleed.

Tell your doctor or healthcare professional if you notice any of the following symptoms.

These are very rare side-effects that happen to less than 1 in 10,000 people taking AUGMENTIN:

- Fever, severe chills, sore throat or mouth ulcers. Unusual joint pains especially if accompanied by a rash.
- The tongue may change colour to yellow, brown or black, or it may have a hairy appearance.

These are rare side-effects that could happen to more than 1 in 10,000 but less than 1 in 1000 people taking AUGMENTIN:

- Bleeding, or bruising, more easily than usual.
- A rash where the spots (usually 0.5 cm to 2 cm in size) have a pink/red ring around the edge and a darker centre.

These are uncommon side-effects that happen to more than 1 in 1000 but less than 1 in 100 people taking AUGMENTIN:

- Mild rash, itching or hives (itchy lumps)
- Indigestion
- Headache
- Dizziness

If any of the following symptoms persist or become

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worse, ask your doctor for advice.

These are common side-effects that could happen to more than 1 in 100 but less than 1 in 10 people taking Augmentin:

- Diarrhoea (loose, or watery bowel movements)
- Nausea (feeling sick).
- Vomiting (being sick)
- Thrush (a fungal infection). In babies this can look like a severe nappy rash. Older children may experience itching and burning around the genital area (private parts) with the presence of a thick, white discharge. Babies and children can also develop thrush in their mouth. This appears as painful white patches on the inside of their mouth and on their tongue.

Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving Augmentin at the beginning of a meal.

Very rarely, children's teeth can become discoloured while using Augmentin. This is less likely to happen if they clean their teeth thoroughly, and any discolouration can usually be removed by brushing. If the discolouration does not disappear, ask your doctor or dentist for advice.

If your child develops any other unusual discomfort or symptoms while taking Augmentin, tell your doctor as soon as possible.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the

website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## Storage and Disposal of AUGMENTIN

### - Storage

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 7 days.

Return left-over medicine to your pharmacist.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

Dry powder for reconstitution in water, at time of dispensing, to form an oral sugar free suspension.

Available in a clear, glass bottles with aluminium screw caps, containing an off-white dry powder. The Augmentin suspension 457 mg/5 ml 35 ml and 70 ml presentations may be supplied with a dosing device.

or  
Single-dose sachets  
When reconstituted, an off-white suspension is formed.

## - Ingredients

- Active ingredient(s)

400 mg amoxicillin trihydrate and 45 mg potassium clavunate in 5 ml.

- Inactive ingredient(s)

Crospovidone, silicon dioxide (anhydrous), carmellose sodium, xanthan gum, colloidal anhydrous silica, magnesium stearate, sodium benzoate, aspartame, strawberry flavour

## - MAL number

MAL07031150AZ

## Manufacturer

SmithKline Beecham Limited  
Clarendon Road Worthing,  
West Sussex, BN 148QH,  
United Kingdom

## Product Registration Holder

GlaxoSmithKline  
Pharmaceutical Sdn. Bhd.  
Level 6, Quill 9,  
112 Jalan Semangat,  
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Selangor, Malaysia

## Date of Revision

-14/04/2016

## Serial Number:

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