Patient Information Leaflet

AUGMENTIN BD SF

Scheduling status: S4

AUGMENTIN BD SF Powder for suspension forte

Amoxicillin 400,0 mg/Clavulanic acid 57,0 mg

Sugar-free

Contains sweetener – each 5 mL contains 12,5 mg aspartame

Read all of this leaflet carefully before you or your child starts taking AUGMENTIN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AUGMENTIN has been prescribed for your child only and should not be shared with other people. It may harm them, even if their symptoms are the same.

What is in this leaflet:

1. What AUGMENTIN is and what it is used for
2. What you need to know before you take AUGMENTIN
3. How to take AUGMENTIN
4. Possible side effects
5. How to store AUGMENTIN
6. Contents of the pack and other information.

1. What AUGMENTIN is and what it is used for:

AUGMENTIN is an antibiotic which contains two active ingredients a penicillin called amoxicillin and clavulanic acid.

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

2. What you need to know before your child can take AUGMENTIN:

Your child should not receive AUGMENTIN if:

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

The safety of AUGMENTIN in children below 2 years of age has not been established.

Warnings and precautions:

Take special care with AUGMENTIN if:

- your child develops a skin rash while taking AUGMENTIN. Do not give any more suspension and tell your doctor at once
- your child has glandular fever (mononucleosis) and he/she is 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 he/she may need to be given a different medicine
- your child suffers from a condition called phenylketonuria (PKU). This is because AUGMENTIN contains aspartame
- your child is not passing urine regularly and not able to drink water.

In some cases, your doctor may investigate the type of bacteria that is causing your child's 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 POSSIBLE SIDE EFFECTS.

Other medicines and AUGMENTIN:

Always tell your healthcare professional if your child is taking any other medicine. (This includes complementary or traditional medicines).

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

- allopurinol
- probenecid
- anti-coagulants (used to prevent blood clots) such as warfarin
- mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).

AUGMENTIN with food or drink:

It is better to give your child AUGMENTIN at the same time as a meal, but AUGMENTIN still works if it is taken without food. Remember to give your child plenty of fluids such as water or non-alcoholic drinks.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine or giving to your child.

Driving and using machines:

AUGMENTIN has no effect on the ability to drive or operate machinery.

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.

3. How to take AUGMENTIN:

Do not share medicines prescribed for your child with any other person.

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

The doctor will decide how much 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 at the start of, or just before, a meal but AUGMENTIN still works if it is given without food.

Make sure the whole dose is swallowed every time.

Once you have started giving AUGMENTIN:

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 than they should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you forget to take a dose of AUGMENTIN:

Give it as soon as you remember, then carry on as before**.**

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects:

AUGMENTIN can cause side effects.

Not all side effects reported for AUGMENTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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:

- sudden wheeziness, shortness of breath, or chest tightness
- swelling of the face, lips, tongue, or other parts of the body
- suddenly feeling faint, especially upon standing up
- convulsions (fits or seizures)
- 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.
- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale, and yellowing of the skin and/or eyes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AUGMENTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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, and it may have a hairy appearance
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- 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))
- 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 all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- mild rash, itching or hives (itchy lumps)
- indigestion
- headache
- dizziness
- 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.

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.

Not all side effects reported for AUGMENTIN are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AUGMENTIN.

5. How to store AUGMENTIN:

Store all medicines out of reach of children**.**

Do not use after the expiry date stated on the label / carton / bottle.

Store in a dry place at or below 30°C in the original packaging. Keep tightly close.

Once made up, the suspension should be stored in a refrigerator (2°C to 8°C). Do not freeze it. Use the suspension within 7 days**.** Return all unused medicine to your pharmacist.

Dispose of any unused suspension 7 days after first making up. Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

AUGMENTIN contains:

The active substances 400,0 mg amoxicillin and 57,0 mg clavulanic acid are present in 5 mL of suspension.

The other ingredients are aspartame, colloidal anhydrous silica, hydroxypropyl methylcellulose, silicone dioxide, succinic acid, xanthan gum, and raspberry, orange and golden syrup dry flavours.

What AUGMENTIN looks like and contents of the pack:

Off-white powder for reconstitution to an off-white suspension with an orange/raspberry flavour

Contents of the pack:

190/200 mL clear, colourless glass bottle containing an off-white powder for reconstitution to 140 mL suspension with a pilfer proof or child resistant closure.

147 mL clear colourless glass bottle containing an off-white powder for reconstitution to 70 mL suspension with a pilfer proof or child resistant closure.

107 mL clear colourless glass bottle containing an off-white powder for reconstitution to 35 mL suspension with a pilfer proof or child resistant closure.

When first reconstituted allow to stand for 5 min to ensure full dispersion. The reconstituted suspension will be white to tan in colour.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

No 1 Bridgeway Road, Bridgeways Precinct

Century City

Cape Town

7441

This leaflet was last revised in:

09 May 2024

Registration Number:

36/20.1.2/0367

GDS 26

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