AUGMENTIN ES 600

Patient information leaflet

Scheduling status:

S4

AUGMENTIN ES 600 Powder for Suspension Extra Strength

Amoxicillin trihydrate equivalent to 600 mg amoxicillin and potassium clavulanate equivalent to 42,9 mg clavulanic acid

Sugar-free.

Contains sweetener: Aspartame 13,60 mg/5 ml

Read all of this leaflet carefully before your child starts taking AUGMENTIN ES 600:

- Keep this leaflet. You may need to read it again.
  If you have any further questions, please ask your doctor or pharmacist nurse or other healthcare provider.
- AUGMENTIN ES 600 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What AUGMENTIN ES 600 is and what it is used for

2. What you need to know before you take AUGMENTIN ES 600

3. How to take AUGMENTIN ES 600

4. Possible side effects

5. How to store AUGMENTIN ES 600

6. Contents of the pack and other information

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. What you need to know before your child can take AUGMENTIN ES 600:

AUGMENTIN ES 600 should not be administered to your child if:

- he/she is allergic to amoxicillin or beta-lactam antibiotics (such as penicillins and cephalosporins) or any of the other ingredients of AUGMENTIN ES 600. 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 ES 600
- he/she has ever had jaundice (yellowing of the skin and/or eyes) or liver disease while taking AUGMENTIN ES 600.

Warnings and precautions:

Take special care with AUGMENTIN ES 600 if:

- your child develops a skin rash while taking AUGMENTIN ES 600. Do not give any more suspension and tell your doctor at once

- your child has glandular fever (mononucleosis) and he/she is 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 he/she 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
- your child is not urinating 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 medicine.

Other medicines with AUGMENTIN ES 600:

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 ES 600 with food and alcohol:

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. Remember to give your child plenty of fluids such as water or non-alcoholic drinks.

Pregnancy and breastfeeding:

If your child is pregnant, or breastfeeding her baby, or if she is taking the contraceptive pill, please consult your doctor, pharmacist or other healthcare professional for advice before giving AUGMENTIN ES 600 to your child.

Driving and using machines:

Undesirable effects may occur which may influence the ability to drive and use machines.

AUGMENTIN ES 600 contains aspartame:

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.

3. How to take AUGMENTIN ES 600:

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

Always take AUGMENTIN ES 600 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your 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.

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:

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 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:

AUGMENTIN ES 600 can have side effects.

Not all side effects reported for AUGMENTIN ES 600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AUGMENTIN ES 600, please consult your healthcare provider for advice.

If your child has any of the following symptoms after taking AUGMENTIN ES 600, 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 o~~f~~ 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
- 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
- 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)).

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 ES 600 at the beginning of a meal.

Very rarely, children's teeth can become discoloured while using AUGMENTIN ES 600. 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 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 or 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 ES 600.

5. How to store AUGMENTIN ES 600:

Store all medicines out of reach of children.

Store powder in a cool, dry place below 25 °C.

Keep the container tightly closed.

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

Store the suspension in a refrigerator, (2 °C to 8 °C) or the product may lose some of its effect. Do not freeze it. Use the suspension within 10 days.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What AUGMENTIN ES 600 contains:

Powder for suspension, when reconstituted according to instructions each 5 ml contains the active substances, amoxicillin trihydrate equivalent to 600 mg amoxicillin and potassium

clavulanate equivalent to 42,9 mg clavulanic acid. The amoxicillin is present as amoxicillin trihydrate and the clavulanic acid is present as potassium clavulanate in a ratio of 14:1.

The other ingredients are aspartame, carboxymethylcellulose sodium 12, colloidal anhydrous silica, silicone dioxide, xanthan gum, and artificial strawberry cream flavour.

What AUGMENTIN ES 600: looks like and contents of the pack:

Clear glass bottles with a pilfer proof or child resistant closure containing off-white powder for reconstitution to suspension.

Off-white powder for reconstitution to an off-white to tan suspension.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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