**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

# ACTIMENTIN ES 600 (600 mg/42,9 mg per 5 ml) powder for oral suspension

**co-amoxiclav (amoxicillin/clavulanic acid)**

**ACTIMENTIN ES 600 contains maltodextrin (glucose) as an ingredient of the flavourant. It also contains 1,92 mg acesulfame potassium (E950) and 0,96 mg saccharin sodium (E954) per 1 ml, as sweeteners.**

**Read all of this leaflet carefully before you start giving your child ACTIMENTIN ES 600.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACTIMENTIN ES 600 has been prescribed for your baby or child. You should not share this medicine with other people. It may harm them, even if their symptoms are the same as your child's.

**What is in this leaflet**

1. What ACTIMENTIN ES 600 is and what it is used for
2. What you need to know before you give ACTIMENTIN ES 600
3. How to give ACTIMENTIN ES 600
4. Possible side effects
5. How to store ACTIMENTIN ES 600
6. Contents of the pack and other information

## 1. What ACTIMENTIN ES 600 is and what it is used for

ACTIMENTIN ES 600 is an antibiotic that works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

ACTIMENTIN ES 600 is used in babies and children 3 months and older to treat infections caused by bacteria.

## 2. What you need to know before you give ACTIMENTIN ES 600

**Do not give ACTIMENTIN ES 600 to your child:**

- if he / she is allergic to amoxicillin, clavulanic acid, penicillin antibiotics or any of the other ingredients of this medicine (listed in section 6).
- if he / she has ever had an allergic reaction when taking any other antibiotic, you should talk to your doctor before you give ACTIMENTIN ES 600. This can include a skin rash or swelling of the face or throat.
- if he / she has ever had liver problems or jaundice (yellowing of the skin and / or eyes) when taking an antibiotic.
- if he / she is under 3 months of age.

**Do not give ACTIMENTIN ES 600 to your child if any of the above applies to your child. If you are not sure, talk to his / her doctor or pharmacist before giving ACTIMENTIN ES 600.**

**Warnings and precautions**

**Take special care and get advice from your doctor if:**

- your child develops a fever with skin rash or watery diarrhoea (usually with blood and mucus, as well as stomach pain) while taking ACTIMENTIN ES 600. **Do not give any more suspension and tell the doctor at once.**

- 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 has glandular fever (mononucleosis) and he / she is prescribed ACTIMENTIN ES 600. Please tell the doctor before you give this medicine.
- your child is taking allopurinol (used for gout), as it may be more likely that he / she will have an allergic skin reaction if used in combination with ACTIMENTIN ES 600.
- your child has been diagnosed with lymphatic leukaemia as your child may be more prone to development of skin rashes due to ACTIMENTIN ES 600.
- if your child is taking anticoagulant medicines (like warfarin) to thin the blood (to prevent blood clots), as your child's dose of anticoagulant may need to be changed to make sure it works as it should.
- your child is not passing water regularly (urinating).
- if your child is going for blood tests (such as red blood cell status tests) or urine tests (for glucose). Let the doctor or nurse know that he / she is taking ACTIMENTIN ES 600 because this medicine can affect the results of these types of tests.

**ACTIMENTIN ES 600 can make some existing conditions worse or cause serious side effects. These include allergic reactions, severe skin rashes, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking ACTIMENTIN ES 600, to reduce the risk of any problems. See '*Conditions you need to look out for'* in Section 4.**

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 co-amoxiclav or a different medicine.

**Other medicines and ACTIMENTIN ES 600:**

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including:

- probenecid (used for gout), as your doctor may decide to adjust the dose of ACTIMENTIN ES 600 or stop ACTIMENTIN ES 600 and switch to another antibiotic.
- allopurinol (used for gout), as it may be more likely that your child will develop an allergic skin reaction.
- anticoagulant medicines (such as warfarin) that thins the blood to prevent blood clots. When anticoagulants are taken with ACTIMENTIN ES 600 extra blood tests may be needed and your child's dose of anticoagulant may need to be changed to make sure it works as it should.
- methotrexate (a medicine used to treat cancer or rheumatic diseases), as ACTIMENTIN ES 600 may change how methotrexate works and increase the side effects due to methotrexate.
- contraceptive pills, as ACTIMENTIN ES 600 may reduce how well the contraceptive pills work.
- mycophenolate mofetil (a medicine used to prevent rejection of transplanted organs), as ACTIMENTIN ES 600 can affect how mycophenolate mofetil works.
- any medicine or product that contains alcohol. Alcohol, if taken with ACTIMENTIN ES 600, may cause a disulfiram-like reaction causing nausea, vomiting, flushing, dizziness, throbbing or severe headache and chest pain. It may be severe, depending on the amount of alcohol ingested.

**ACTIMENTIN ES 600 with food, drink and alcohol**

ACTIMENTIN ES 600 should be given to your child just before a meal (see section 3: *How to give ACTIMENTIN ES 600*).

Alcohol or alcohol containing products, including medicines, should not be taken / given during this antibiotic course. It can cause a disulfiram-like reaction causing nausea, vomiting, flushing, dizziness, throbbing or severe headache and chest pain. This may be severe, depending on the amount of alcohol ingested.

**Pregnancy, breastfeeding and fertility**

If your child who is about to take ACTIMENTIN ES 600 is pregnant or breastfeeding, think she may be pregnant or taking a contraceptive pill, please consult your doctor, pharmacist or other health care provider for advice before giving ACTIMENTIN ES 600 to your child.

**Driving and using machines**

It is not always possible to predict to what extent ACTIMENTIN ES 600 may interfere with your child's daily activities. Do not let your child engage in activities that requires mental alertness, judgment and / or sound coordination and vision until you are aware of the measure to which ACTIMENTIN ES 600 affects him / her.

ACTIMENTIN ES 600 can have side effects such as allergic reactions, dizziness or fits that interferes with your child's ability to perform certain activities such as riding bikes, climbing or using machinery / equipment.

**ACTIMENTIN ES 600 contains maltodextrin, acesulfame potassium and saccharin sodium**

ACTIMENTIN ES 600 contains maltodextrin as an ingredient of the strawberry flavourant. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicine.

ACTIMENTIN BD 600 contains acesulfame potassium and saccharin sodium as sweeteners.

**3. How to give ACTIMENTIN ES 600**

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

Always give ACTIMENTIN ES 600 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Your doctor will decide how much ACTIMENTIN ES 600 you should give to your baby or child, and for how many days you should give it (usually 10 days).
- Doses are worked out depending on the child's bodyweight in kilograms.
- You may be provided with a plastic measuring spoon or syringe to assist you in giving your child the correct dose of ACTIMENTIN ES 600.
- Always shake the bottle well before each dose.
- ACTIMENTIN ES 600 should be taken just before a meal.

Your doctor will tell you how long your treatment with ACTIMENTIN ES 600 will last. Do not stop treatment early because your child feels better.

If you have the impression that the effect of ACTIMENTIN ES 600 is too strong or too weak, tell your doctor or pharmacist.

**If your child has taken more ACTIMENTIN 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 centre.

If you have given your child too much ACTIMENTIN ES 600, or if your child has accidently taken ACTIMENTIN ES 600, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions (fits). It is important to give plenty of water to drink, to stop giving ACTIMENTIN ES 600 and contact the doctor as soon as possible. Take the medicine bottle to show the doctor.

**If you forget to take a dose of ACTIMENTIN ES 600**

If you forget to give your child a dose, give it as soon as you remember, then carry on as before; however, do not give a double dose to make up for a forgotten dose.

**If your child stops taking ACTIMENTIN ES 600**

Keep giving your child ACTIMENTIN ES 600 until the treatment is finished, even if he / she feels better. Do not stop when your child feels better. Your child needs every dose to help fight the infection.

**4. Possible side effects**

ACTIMENTIN ES 600 can have side effects.

Not all side effects reported for ACTIMENTIN ES 600 are included in this leaflet. Should your child's general health worsen or he / she experiences any untoward effects while taking ACTIMENTIN ES 600, please consult your health care provider for advice.

***Conditions you need to look out for***

**If your child has any of the following symptoms after taking ACTIMENTIN ES 600, stop giving it and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- sudden wheeziness, shortness of breath or chest tightness.
- swelling of the face, lips, tongue, other parts of the body or / and suddenly feeling faint, especially upon standing up.
- convulsions (fits or seizures).
- yellowing of the skin and / or eyes, or dark coloured urine, which may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may indicate liver problems and sometimes may not occur until several weeks after the end of treatment. It can be severe.
- blood in the urine, with a rash, fever, exhaustion / fatigue, confusion, water retention and swelling.
- 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, or a rash accompanied by fever, which may or may not be accompanied by body aches, flu-like symptoms and swollen glands.
- dark urine, unusual tiredness or weakness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and / or eyes.
- fever, headache, nausea and vomiting, dislike for bright light and stiff neck, which may or may not be accompanied by seizures (fits) and / or a rash. These symptoms may indicate that your child has meningitis, which is inflammation of the lining of the brain.

These are all serious side effects. Your child may have had a serious reaction to or side effect from ACTIMENTIN ES 600 and may need urgent medical attention or hospitalisation.

**Tell your doctor or health care provider if you notice any of the following symptoms:**

- fever, severe chills, sore throat or mouth ulcers, with or without unusual joint pains, especially if accompanied by a rash.
- tongue that changes colour to yellow, brown or black, and it may have a hairy appearance.
- bleeding, or bruising, more easily than usual.
- 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).

**If any of the following symptoms, which occur frequently with ACTIMENTIN ES 600 use, persist or become worse, ask your doctor for advice:**

- diarrhoea (loose or watery bowel movements), nausea (feeling sick) or / and vomiting (being sick). Nausea occurs more frequently at high doses. Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving ACTIMENTIN ES 600 at the beginning of a meal.
- 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.

**If your child develops any other unusual discomfort or symptoms while taking ACTIMENTIN ES 600, tell your doctor as soon as possible.**

Other side effects of ACTIMENTIN ES 600 include:

*Less frequent side effects:*

- mild skin rash, itching or raised itchy rash (hives).
- indigestion.
- dizziness and headache.
- changes in blood tests for example low number white blood cells or platelets, or changes in liver enzymes.

*Side effects, with an unknown frequency:*

- hyperactivity.
- tooth discolouration. Rarely, children's teeth can become discoloured while using ACTIMENTIN 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.
- crystals in urine.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 this medicine.

**5. How to store ACTIMENTIN ES 600**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Dry powder: store at or below 25 °C.
- Reconstituted suspension: store in a refrigerator (2 ˚C – 8 ˚C). Do not freeze. Once made up, the suspension should be used within 7 days.
- Store in the original container.
- Dry powder: Do not use after the expiry date printed on the label or carton.
- 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 ACTIMENTIN ES 600 contains**

The active substances are amoxicillin and clavulanic acid. Once reconstituted (made up), each 1 ml of suspension contains amoxicillin trihydrate equivalent to 120 mg amoxicillin and potassium clavulanate equivalent to 8,58 mg of clavulanic acid.

The other ingredients are acesulfame potassium (E950), carmellose sodium, colloidal anhydrous silica, crospovidone, type A, silicon dioxide, xanthan gum, saccharin sodium (E954), strawberry flavour containing maize maltodextrin, propylene glycol and triethyl citrate.

**What ACTIMENTIN ES 600 looks like and contents of the pack**

ACTIMENTIN ES 600 is a white to yellowish powder with strawberry flavour packed in glass bottles, with a dosing device (either a spoon, cup or syringe) packed in outer cartons. Once made up (reconstituted), the bottle contains 30 ml, 50 ml, 70 ml or 100 ml of an off-white to yellowish coloured suspension with strawberry odour.

Not all pack sizes may be marketed.

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