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<b>Version: 1</b>		
<b>Artwork Information Panel (AIP)</b>		
<b>Manufacturing Site Number:</b> 6200000092484		
<b>Manufacturing Site(s):</b> GSK_MAYENNE_FRANCE		
<b>Product Market Trade Name:</b> AUGMENTIN		
<b>Approving Market(s):</b> MARKET GROUP-Gulf and Near East		
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200 mm Measuring Bar

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NOTE TO MARKET

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Package leaflet: Information for the user

**AUGMENTIN 62.5 mg/ml Infant Drops**  
(Amoxicillin trihydrate - Potassium clavulanate)  
Powder for oral suspension

6200000092484

**Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for them.**

- Keep this leaflet. You may want to read it again.
- If you have any further questions, ask your doctor, pharmacist or a nurse.
- This medicine is usually prescribed to a child. Do not pass it on to others. It may harm them, even if they have the same symptoms as your child.
- If your child gets any side effects, contact your doctor, pharmacist or a nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Augmentin is and what it is used for?
2. What you need to know before using Augmentin?
3. How to use Augmentin?
4. What are the 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 that works by killing bacteria that cause infections. It contains two different active ingredients, amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes become inactive. The second active ingredient (clavulanic acid) prevents that. Augmentin is used in the treatment of the following infections in infants and children:

- Otitis media infections and infections of the paranasal sinuses
- Respiratory infections
- Urinary tract infections
- Skin and soft tissue infections including dental infections
- Bone and joint infections.

**2. What you need to know before using Augmentin?**  
You should not use Augmentin for your child in the following cases:

- If your child is allergic to amoxicillin, clavulanic acid, penicillin or any other ingredients of this medicine (see list in section 6).
- If your child has ever had a severe allergic reaction to any other antibiotic. This may have been a rash or swelling of the face or throat.
- If your child has ever had liver problems or jaundice (yellowing of the skin) while taking an antibiotic.

→ **Do not give Augmentin to your child if any of these statements apply to your child.** Talk to your doctor or pharmacist before using Augmentin if you are not sure.

**Warnings and Precautions**  
Please talk to your doctor, pharmacist or a nurse before giving Augmentin to your child if your child:

- has Pfeiffer's glandular fever
- is being treated from liver or kidney problems
- has irregular water levels disorder.

Talk to your doctor or pharmacist before using Augmentin if you are not sure whether any of these cases apply to your child. In certain cases, your doctor may determine the type of bacteria that causes your child infection. Depending on the results, your child may have a different strength of Augmentin or another medicine.

**Conditions you need to look out for**  
Augmentin can make some existing conditions worse, or lead to serious side effects. These include allergic reactions, seizures and inflammation of the large intestine. You must look out for certain symptoms while you are giving your child "Augmentin", in order to reduce the risk of side effects. See "Conditions you need to look out for" in Section 4.

**Blood and urine tests**  
If your child has blood tests (such as a red blood cell test or determination of liver function) or urine tests (for glucose), tell your doctor or nurse that your child takes Augmentin. This is necessary because Augmentin can influence the results of these tests.

**Augmentin and Other medicines**  
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. If your child takes Allopurinol (to treat gout) with Augmentin, there is more probability to have an allergic skin reaction. If your child takes Probenecid (to treat gout), your doctor may decide to adjust the dose of Augmentin. If your child is taking medicines to help prevent blood clots (such as warfarin) with Augmentin, additional blood tests may be needed. Augmentin may affect the efficacy of methotrexate (a medicine used to treat cancer or rheumatic diseases). Augmentin may affect the efficacy of mycophenolate mofetil (a medicine used to prevent rejection of transplanted organs).

**Pregnancy, lactation and fertility**  
If the patient is likely to be pregnant, nursing, suspected of being pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Effects on Ability to Drive and Use Machines**  
Augmentin may cause side effects and these symptoms may affect your ability to drive. Do not drive a vehicle or operate machines if you do not feel comfortable.

**Augmentin contains aspartame and maltodextrin**

- Augmentin contains aspartame (E 951) as a source of phenylalanine and may be harmful for children born with a condition called phenylketonuria, a rare congenital condition in which phenylalanine accumulates because the body cannot sufficiently break it down.
- Augmentin contains traces of benzyl alcohol. May cause allergic reactions.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to certain sugars, contact your doctor before using this medicine.

**3. How to take Augmentin?**  
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults and children weighing 40 kg and over**

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

**Children weighing less than 40 kg**  
All doses are calculated based on the body weight of the child in kilograms.

- Your doctor will tell you how much Augmentin you should give to your child.
- You will receive a plastic dosing syringe CE. Instructions for the use of the dosing syringe can be found at the end of this leaflet. You should use it to give your child the correct dose.
- Recommended dose - 20 mg/5 mg (Amoxicillin trihydrate/Potassium clavulanate) to 60 mg/15 mg (Amoxicillin trihydrate/Potassium clavulanate) per kilogram of the body weight per day given in three divided doses.

**Patients with kidney or liver problems**

- If your child has kidney problems, the dose may be reduced. Different strength or different medicine may be chosen by your doctor.
- If your child has liver problems, blood tests may be more frequent to monitor liver function.

**Instructions for use:**

- Always shake the bottle well before each dose.
- Take it with a meal.
- Take the doses evenly throughout the day with a gap of at least 4 hours. Do not use 2 doses within 1 hour.
- Do not use Augmentin for your child for more than 2 weeks. Visit your doctor again if your child does not feel better.

**If you take more Augmentin than you should (Overdose)**  
If you have used too much Augmentin for your child, he/she may experience stomach problems (nausea, vomiting or diarrhea) or seizures. Contact your doctor as soon as possible. Take the medicine bottle with you and show it to the doctor.

**If you forget to take Augmentin**  
If you forget to give your child's dose, give it to your child as soon as you remember. You should not give the next dose too soon, but you should then wait about 4 hours before giving the next dose. Do not double the amount if you have forgotten to give the previous dose.

**If your child stops taking Augmentin**  
Keep giving your child Augmentin until the treatment is finished, even if he/she already feels better. Your child needs all the prescribed doses to fight the infection. If some bacteria survive, they can cause the infection to recur.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. What are the possible side effects?**  
Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur when taking this medicine.

**Conditions you need to look out for**

**Allergic reaction:**  
(≥ 1/1,000 to ≤ 1/100)

- Skin rash
- Inflammation of blood vessels (*vasculitis*), which may manifest in red or purple raised spots on the skin, but can also affect other areas of the body
- Fever, joint pain, enlarged lymph nodes in the neck, armpits or groin
- Swelling, sometimes on the face or throat (*angioedema*) causing breathing problems
- Collapse.
- Chest pain associated with allergic reactions, which may be a symptom of an allergic-related heart attack (Kounis syndrome)

→ **Contact a doctor immediately** if any of these symptoms occur to your child. **Stop taking Augmentin.**

**Inflammation of the large intestine**  
An inflammation of the large intestine that causes watery diarrhea, usually with blood and mucus, stomach pain and / or fever. Drug-Induced Enterocolitis Syndrome (DIES)  
THIS has been reported mainly in children who have received amoxicillin/clavulanic acid. It is a specific type of allergic reaction with the leading symptom of persistent vomiting (1-4 hours after administration of the drug). Other symptoms may include abdominal pain, lethargy, diarrhea, and low blood pressure. If you have severe and persistent abdominal pain, it could be a sign of acute pancreatitis. → **Ask your doctor for advice as soon as possible** if you experience these symptoms with your child.

**Very common side effects**

- In more than 1 person in 10
- Diarrhea (in adults).

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**Common side effects**  
1 to 10 users out of 100

- Fungal infection (*Candida* - yeast infection in the area of vagina, mouth or skin folds)
- Nausea, especially when taking high doses
  - Give Augmentin with a meal if this is applied
- Vomiting
- Diarrhea (in children).

**Uncommon side effects**  
1 to 10 users out of 1,000

- Skin rash, itching
- Loftier itchy rash (*wheals*)
- Upset stomach
- Dizziness
- Headache.

Uncommon side effects that may show up in blood tests:

- Increase of some substances (*enzymes*) produced by the liver as an indication of liver damage.

**Rare side effects**  
1 to 10 people out of 10,000

- Skin rash, possibly with blisters that looks like small targets (central dark spot with surrounding paler area and a dark ring around - *erythema multiforme*)
- Contact a doctor urgently if this side effect occurred to your child.

Rare side effects that may show up in blood tests:

- Low number of cells involved in blood clotting
- Low number of white blood cells.

**Frequency not known**  
Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the meninges (*aseptic meningitis*)
- Serious skin reactions:
  - Extensive rash with blisters and peeling of the skin, especially around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*) and a more severe form causing extensive skin peeling (more than 30% of the body surface area) (*toxic epidermal necrolysis*)
  - Extensive red rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
  - Red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
  - Flu-like symptoms with rash, fever, swollen glands and abnormal blood levels (including increased levels of white blood cells [Eosinophilia] and liver enzymes) (drug reaction with Eosinophilia and systemic symptoms [DRESS]).

→ **Contact a doctor immediately if any of these side effects occur in your child.**

- Rash with circularly arranged vesicles with central crusting or similar to a string of beads (linear IgA disease)
- Inflammation of the liver (*Hepatitis*)
- Jaundice caused by an increase in bilirubin (a substance produced by the liver) in the blood, which can cause yellowing of your child's skin and white-eye areas
- Inflammation of renal tubules
- delaying blood clotting
- hyperactivity
- Seizures (in people taking high doses of Augmentin or having kidney problems)
- Black, hairy-looking tongue
- Discoloration of teeth (in children), usually can be removed by brushing.

Side effects that may show up in blood or urine tests:

- Severe reduction in the number of white blood cells
- Low number of red blood cells (*hemolytic anemia*)
- Crystals in the urine.

**Report of side effects**

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.
- To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: [gulf.safety@gsk.com](mailto:gulf.safety@gsk.com).

**5. How to store Augmentin?**  
Store medicinal products out of reach of children.

**Dry powder**  
Store in the original package to protect from moisture.  
Store at or below 30°C.  
Do not use this medicine after the expiry date which is stated on the outer carton after "EXP". The expiry date refers to the last day of the specified month.

**Prepared suspension**  
Store in a refrigerator (2-8°C).  
Do not freeze.  
The prepared suspension should be used within 7 days.  
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Augmentin contains**

- The active ingredients are: Amoxicillin Trihydrate / Potassium Clavulanate
- 1 ml of prepared suspension contains 57.4 mg amoxicillin trihydrate equivalent to 50 mg amoxicillin and 15 mg potassium clavulanate, equivalent to 12.5 mg clavulanic acid.
- List of Excipients:  
Aspartame (E 951), xanthan gum, silica, colloidal silica, succinic acid, hypromellose, orange flavour 1 \* (contains benzyl alcohol), orange flavour 2 \*, raspberry flavour \* and gold syrup flavour \*.
- \* It contains maltodextrin.
- See section 2 for more information on aspartame, benzyl alcohol and maltodextrin in Augmentin.

**What Augmentin looks like and contents of the pack**  
Augmentin 62.5 mg/ml infant drops are a cream-colored powder that is in a clear glass bottle.  
After preparation, the bottle contains 20 ml of a cream-colored mixture, called a suspension.

**Manufacturer**  
Glaxo Wellcome Production\*, 53100 Mayenne, France  
\*member of GSK group of companies.

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**Advice/medical education**  
Antibiotics are used to treat bacterial infections. They are ineffective against viral infections. Sometimes a bacterial infection does not respond to antibiotic treatment. One of the most common reasons for this is that the bacteria that cause the infectious disease are resistant to the antibiotic used. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many different reasons. Cautious use of antibiotics can help reduce the risk of bacteria becoming resistant. If your doctor prescribes antibiotic treatment, it is only for the purpose of treating your current case. The following advice will help to prevent the emergence of resistant bacteria that may inhibit the action of the antibiotic.

- It is very important that you take the antibiotic at the right dose, at the right times and for the right duration. Read the instructions on the label and ask your doctor or pharmacist if you do not understand anything.
- You should not take an antibiotic if it was not specifically prescribed for you and you should only use it for the treatment of the infection for which it was prescribed.
- You should not take any antibiotics that have been prescribed for other people, even if they had a similar infection.
- You should not give antibiotics that you have been prescribed on to other people.
- If you have any of the antibiotics left after stopping treatment as directed by your doctor, you should take the unused antibiotic to a pharmacy for proper disposal.

**Preparation Instructions**  
Before using, check that the cap's seal is intact. Shake the bottle to loosen the powder. Add the indicated amount of water (see instructions below), turn the bottle over and shake well.  
Using the dosing device, 18 ml of water (3 x 5 ml and 1 x 3 ml) can be measured.  
Alternatively, shake the bottle to loosen the powder and then fill the bottle with water just below the mark on the bottle or label, turn it over and shake well. Then fill up to exactly this mark with water, turn it over and shake well again.

Strength	Volume of Water to be added to prepare (ml)	Final volume of prepared oral suspension (ml)
50 mg/12.5 mg/ml	18	20

Shake the bottle well before each use.

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists



