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**Formulation Tablet embossing** Storage conditions **Shelf Life** 

### NOTE TO MARKET

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## GSK

# AUGMENTIN 62.5 mg/ml Infant Drops

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.

  at is in this leaflet:
  What Augmentin is and what it is used for?

\*\*What is in this leaflet:

1. What you need to know before using Augmentin?

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?

1. What Augmentin is and what it is used for?

1. What Augmentin is and what it is used for?

1. What Augmentin is and what it is used for?

1. What Augmentin is an antibiotic that works by killing bacteria that cause infections. It contains two different active ingredients, amoxicillin and clavulanic acid. Amox 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:

• Oiths media infections and infections of the paranasal sinuses

• Respiratory infections

• Urinary tract infections

• Urinary tract infections

• Skin and soft itssue infections including dental infections

Respiratory inrecurs
Urinary tract infections
Skin and soft tissue infections including dental infections
Bone and joint infections.

What you need to know before using Augmentin?
You should not use Augmentin for your child in the following cases:
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 is allergic to amoxicillin, clavulanic acid, penicillin or 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 Plefifler'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.

Augmentin or another medicine.

Conditions you need to look out for

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.

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.

In your child has blood tests (such as a red blood cell test or determination of liver function) of unne tests (for glucose), tell your doctor or nurse that your child takes Augmentin and Other medicines

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 Probenecic (do 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 (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 aspartame (E 951) as a source of phenylalanine and sufficiently break it down.

Augmentin contains traces of benzyl alcohol. May cause allergic reactions.

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 upon this producine.

your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- 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 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 kilorely problems, the dose may be reduced. Different strength or different medicine may be chosen by your doctor.

   If your child has kilorely 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, 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 take Augmentin

  If you forget to take Augmentin

  If you forget to take Augmentin (he/she may experience stomach problems (nausea, vomiting or diarrhea) or seizures. Contact your doctor as soon as pos ure member. You should not give the next dose to

(§ 171,000 to § 17 tou)

Skin rask

Inflammation of blood vessels (vasculiits), 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 Entercocilis 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. acute inflammation of the pancreas (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

Page 1 **FRONT** 

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## NOTE TO MARKET

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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 richy 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 62000000092484

Inflammation of the large intestine (see above)

Inflammation of the meninges (aseptic meningits)

Serious skin reach with bilisters and peeling of the skin, especially around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) and a more sew causing extensive skin peeling (more than 30% of the bord surface areal travia and large intestine (see above) and some peeling of the skin, especially around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) and a more sew causing extensive rash with blisters and peeling of the skin, especially around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) and a more sew causing extensive skin peeling (more than 30% of the bordy surface areal travia called the service and the servic

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 40% of the body surface area) (toxic epidermal necrolysis)
Extensive red rash with blisters (bullous exfoliative dermatitis)
Red, scaly rash with bumps under the skin and blisters (bullous exfoliative dermatitis)
Red, scaly rash with bumps under the skin and blisters (seanthemous 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 (\*Iripatitis\*)
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 (\*Iring in the urine.\*\*)
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.safet

Prepared suspension Store in a refrigerator (2-8°C).

50 mg/12,5 mg/ml

Store in a refrigerator (2-6°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
What Augmentin contains

thems of the particle 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.

1 ml of prepared suspension contains 57.4 mg arroxicilint uniquiate equivalent to 60 mg arroxicilint and 1 ml of prepared suspension contains 57.4 mg arroxicilint uniquiate equivalent to 60 mg arroxicilint and 1 ml of prepared suspension 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.

\*\*More Augmentin looks like and contents of the pack

See section 2 for more information on aspartame, benzyl alcohol and maitodextrin in Augifuntal 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.

Augmentin 62.5 mg/ml intait unique —— After preparation, the bottle contains 20 ml of a cream-Manufacturer Glaxo Wellcome Production\*, 53100 Mayenne, France

Glaxo Wellcome Production, 35100 Megomor, management, member of SGK 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 according to the properties of the properties of the antibiotic stor many different reasons. Cautious use of antibiotics and 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.

1. 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.

2. 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.

3. You should not take any antibiotics that have been prescribed for other people, even if they had a similar infection.

4. You should not give antibiotics that you have been prescribed on to other people.

5. 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.

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. Final volume of prepared oral suspension (ml) Volume of Water to be added to prepare (ml) Strength

Shake the bottle well before each use.

This is a Medicament 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.

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Council of Arab Health Ministers

Page 2

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- يدال عن مساكل في الكدا أو الكلى

تحدث إلى طبيك أو الصيدلي قبل استخدام أوجدتتين إذا لم تكن متأكدًا مما إذا كانت أي من هذه الأعراض تنطبق على طفلك أم لا.

تحدث إلى طبيك أو الصيدلي قبل استخدام أوجدتين إذا لم تكن متأكدًا مما إذا كانت أي من هذه الأعراض تنطبق على المتالج إصداد طبيك في بعض المحالات التراسية والمتالج إصداد المتالج إصداد المتالج إصداد المتالج إلى عدول المتالج إصداد المتالج إلى عدول المتالج إلى عدول المتالج ال تحقول الجبيد راجع المحادة المساحة في من العمراء أو تحديد وطائف الكبار (الجاوكرز)، يجب عليك حينها أن تغير طبيبك أو معرضتك أن طفلك ينتول عقار أوجمتين. هذا أمر ضروري لأن أوجمتين يمكن أن أوجمتين يمكن أن أوجمتين المحادة أو تحديد وطائف الكبرا أو قد ينتولها وهزا المحادة أو من عقار أوجمتين على الأرجم القرب أن قد وهذا المواحدة والمواحدة والمواحدة أو المواحدة أي المواحدة أو أو المواحدة أو · لا تمنخد أوجيشتن لطفاك لاكلر من أسبوعين. بهب زيارة طبيك مرة أخرى إذا لم يشعر طفاك بتحسن. فقول العرج قار المتلفت هريم في أجيشتن لقرط مها والمجهد المستوات از استين اختمه منطقة بمجور ل تشكر احضية برخم . و يسمع بشوى مع استيه عي وف يميز خمة، حيث يوبيه بعد ارتشار نشد ه استيام كل المراجعة السامع الما المراجعة المستواه المس - بي ره سر سجمييه المحمدة: مثل جميع الأمرية، يمكن أن يتسبب هذا الدواء في حدوث أثار جانبية، وذلك على الرغم من عدم حدوثها مع الجميع. من المحتمل حدوث الأثار الجانبية الثالية عد استخدام هذا الدواء. حالات يشغي الاثنياء فها عقاعات المصادمية: (≥ 1/1,000 to ≤ 1/100) ۱/ ۱ حکال ۱/ ۱ کا ۱/ ۱ کا ۱/ ۱ کا ۱ کا الته و نظیر علی شکل بقع حمراء أو أرجوانية مرفوعة علی الجلد، ولکنه يمکن أن يؤثر أيضنا علی مذاطق آخری من الجسم. التمب أم المفاصل، تضخم العقد الدفاوية بالرقية، الإبطين أو الأربية تورم بني بعدس الأجيان علی ألوجه أو أحلق أرفضة و علتها مما بسبب مصعرية النتفس الانجماء. الانجماء المصدر برنيط بقناعلات حساسية، والتي قد تكون من اعراض الحساسية المرتبطة بنوية قلبية (مثلازمة كوتيس) تتصل بالطبيب علی القور فی حداثة ظهور رئي من هذه الاعراض علی طناك. توقف حينها عن استخدام أوجهنتين. ر رحوس سدهم عن الادوية (DIEs) من الدوية (DIEs) عن هذا بشكل رئيس الكلافو لانوك. إنها ذ الأمرك من هذا بشكل رئيس عند الأطفال الثنين تلقوا أمركسيسولين / حمض الكلافو لانوك. الأخرى الأمرك المؤلفات المقطولة والإمهال، وانخفاض صغط الدم. الشهاب البنكوياس الحاد. إذ المكند عنه يتم من الأم شديدة ومستمرة على البطران بقدون نلك علامة على الشهاب البنكوياس الحاد. المؤلفات الأماد المؤلفات الأماد المؤلفات بسبب الإمهاب الشائبية، وعداد عم الدم والمنحلة والأم في الصدة ورأل الا تشار بطبيقة شامعة جدا

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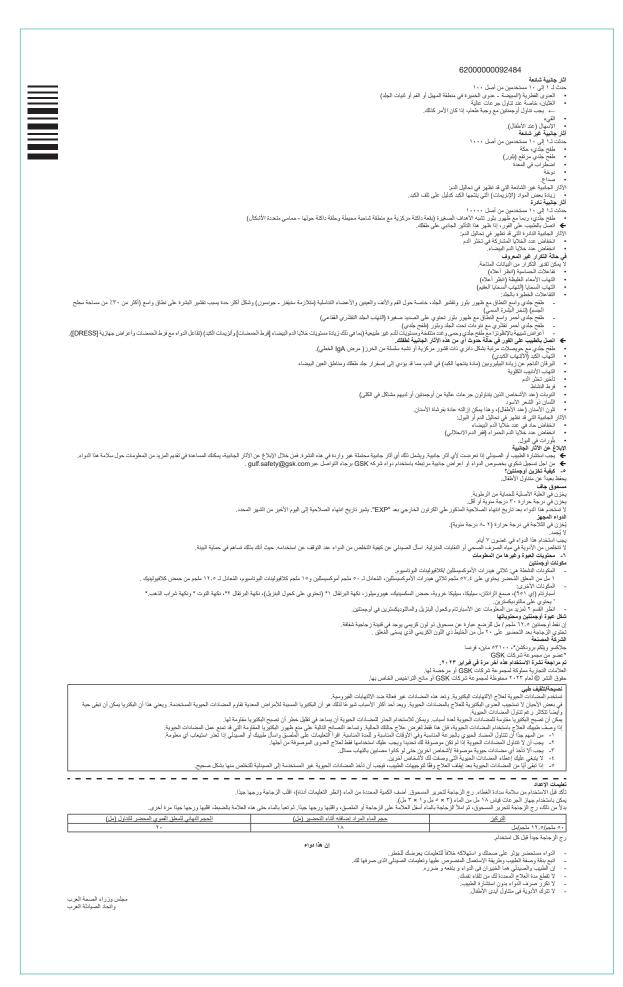
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