

Prescribing Information for Qatar
Augmentin 1 g Film-coated tablets
Amoxicillin trihydrate + potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Augmentin contains the medicines amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium salt). The detailed composition of the different film-coated tablets sold is as follows:

1 film-coated tablet contains:	Amoxicillin	Clavulanic acid	The ratio of Amoxicillin to Clavulanic acid	Ingredients
Augmentin 1 g (875/125) film-coated tablets	875 mg	125 mg	7 : 1	Ingredients for preparation of the film-coated tablets

PHARMACEUTICAL FORM

Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic in the group of penicillins. It contains two medicines called clavulanic acid and amoxicillin.

Clavulanic acid can overcome the main mechanism of resistance of many bacteria that are resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This action means that Augmentin is effective against many bacterial infections.

Augmentin should only be used when prescribed by a doctor for the exclusive treatment of the following bacterial infections:

- Nose, throat, tonsil, front/maxillary sinus and ear infections;
- Respiratory infections (bronchi and lungs);
- Infections of the kidneys, bladder and urinary tract;
- Infections of the genital organs (gonorrhoea, secretion of mucus);
- Gynaecological infections;
- Infections of the skin and soft tissues (boils, abscesses, etc.).

Posology and Method of Administration

Usual dosage

Augmentin is best taken at the start of a meal, with at least half a glass of water. This will ensure optimal action and tolerability. Unless prescribed otherwise by the doctor, the dosage is as follows:

Adults

Mild, moderate and severe infections:

- 2 x daily Augmentin 1 g (875/125)

Once started, antibiotic therapy should be continued as long as prescribed by the doctor.

The signs of illness often disappear before the infection has been completely cured. Therefore, do not stop therapy early, even if you feel better.

Do not change from the prescribed dose. If you believe that the medicine is too weak or too strong, talk to your doctor or pharmacist

Contraindications

You should not take Augmentin if you had an allergic reaction previously to Augmentin, penicillin or cephalosporin. An allergy or hypersensitivity manifests as symptoms such as red spots on the skin, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. hives) and mucous membranes, skin rashes or a painful tongue.

In cases of known or suspected hypersensitivity to any of the other ingredients of the medicine, Augmentin must not be used.

You must not take Augmentin if you have mononucleosis or lymphocytic leukaemia.

Warnings and Precautions

This medicine has been prescribed for you by your doctor to treat your current disease.

The antibiotic in Augmentin is not effective against all micro-organisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it for the treatment of other diseases or other people. You must also not use it for subsequent new infections without consulting a doctor.

The signs of illness often disappear before the infection has been completely cured. This means that the treatment must not be interrupted early, even if you feel better.

Depending on the circumstances and as instructed by the doctor, the treatment may last up to two weeks or longer.

This medicine may affect responsiveness and the ability to drive and use tools or machines.

If you are taking an oral contraceptive (the pill), its efficacy may be reduced during antibiotic therapy. This also applies to Augmentin. Therefore, your doctor or pharmacist can recommend additional contraceptive measures.

Indigestion may occur during the use of Augmentin. In severe gastrointestinal disturbances, with vomiting and diarrhoea, the medicine should be stopped and the doctor should be seen immediately. A doctor should also be contacted if a skin rash or itching appears.

If diarrhoea occurs, no medicine that inhibits intestinal peristalsis (intestinal motility) must be taken.

If you have allergies, allergic asthma, hay fever or hives, special caution is advised when using Augmentin due to possible hypersensitivity reactions.

Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric) are more prone to rashes.

Check with your doctor if you have a kidney function disorder; he/she will prescribe a dosage tailored to fit your needs and it may differ from those shown in the "Usual dosage" section below.

Check with your doctor if you are using blood thinners (anticoagulants).

Check with your doctor if you are using mycophenolate mofetil-containing medicines given following organ transplants as prophylaxis for acute graft rejection reactions.

If you are taking medicines containing digoxin, you must inform your doctor or pharmacist.

Extreme caution is required in cases of decreased kidney or liver function.

Check with your doctor or pharmacist if you

- have other diseases,
- have allergies or
- are taking or applying other medicines (including over-the-counter drugs) externally.

Pregnancy and breast-feeding

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 1 g Film-coated tablets

Amoxicillin trihydrate + potassium clavulanate

Content Lab Code: PI-6708

Date of Preparation: September 2020

Pregnancy

The use of medicines of any kind should be decided during pregnancy with the greatest caution and only after consulting your doctor or pharmacist. In studies in pregnant women with premature rupture of the membranes, preventive treatment with Augmentin has been reported to be associated with an increased risk of sometimes serious tissue-damaging inflammatory bowel disease in the newborn.

Breast-feeding

Because Augmentin is excreted in small amounts in breast milk, there is the possibility of a hypersensitivity reaction (with symptoms such as rash and fever) or diarrhoea in the infant. Therefore, Augmentin should not be taken during breast-feeding or should be stopped.

In any case, see your doctor or pharmacist if you are or could be pregnant or are breast-feeding. They are the only ones who can decide whether you can take Augmentin during those periods.

Possible side effects

Gastrointestinal disorders such as stomach discomfort or queasiness. Reactions such as nausea, loss of appetite, bloating, vomiting, diarrhoea, loose stools, dyspepsia, abdominal pain and inflammation of the tongue or oral mucosa may also occur.

Gastrointestinal symptoms are less common when Augmentin is taken at the start of a meal.

Allergic reactions are common with Augmentin, as with all medicines in the group of penicillins.

Rashes, redness, itching and urticaria (hives) may occur.

Fungal infections of the skin/mucous membranes may also occur.

Dizziness and headaches can sometimes occur.

In rare cases, hyperactivity, agitation, anxiety, insomnia, confusion, behavioural changes, light-headedness, seizures and sensory disturbances can occur.

Superficial tooth discolouration has been observed in rare cases. This usually disappeared with brushing.

Very rarely, a dark-coated tongue, hyperkinesia (excessive locomotor activity), blood count changes, prolongation of bleeding time and prothrombin time, liver inflammation (hepatitis), inflammation of the kidneys and kidney function disorders have been observed.

When administering amoxicillin between the ages of 0 and 9 months, enamel damage (such as white streaks, discolouration) of the permanent incisors cannot be excluded.

Jaundice has been reported rarely.

See your doctor immediately if the following occur:

- Hives, skin rash over large areas of the skin reddening of the skin;
- Yellowish colour of the skin or white part of the eyes;
- Sudden onset of stomach pain or vomiting;
- Severe, bloody or persistent diarrhoea;
- Breathing problems in the form of asthma attacks and hay fever.

If you notice side effects not described here, you must inform your doctor or pharmacist.

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PHARMACEUTICAL DATA

List of Excipients

Colloidal silicon dioxide, sodium starch glycollate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicon oil).

Contents of the pack.

Available in pharmacies against a doctor's prescription that may only be filled once.

Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets.

Special Precautions for Storage

Store in a dry place at or below 30°C.

Store in the original package in order to protect from moisture.

Tablets in desiccated pouch packs should be used within 14 days of opening.

If you notice any discolouration of the Augmentin film-coated tablets, there may have been a change in the medicine. If this happens, see your doctor or pharmacist immediately.

Do not use this medicine after the expiry date which is stated on the pack after "EXP".

See your doctor or pharmacist for further information. These people have detailed information for specialists.

Manufactured by:

SmithKline Beecham Limited*
Worthing, United Kingdom

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Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: June 2015.

Abbreviated Prescribing Information for Qatar
Augmentin 1 g Film-coated tablets
Amoxicillin trihydrate + potassium clavulanate

Package leaflet QUALITATIVE AND QUANTITATIVE COMPOSITION: Augmentin contains the medicines amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium salt). **PHARMACEUTICAL FORM:** Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is an antibiotic in the group of penicillins. It contains two medicines called clavulanic acid and amoxicillin. Clavulanic acid can overcome the main mechanism of resistance of many bacteria that are resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This action means that Augmentin is effective against many bacterial infections. Augmentin should only be used when prescribed by a doctor for the exclusive treatment of the following bacterial infections: Nose, throat, tonsil, front/maxillary sinus and ear infections; respiratory infections (bronchi and lungs); infections of the kidneys, bladder and urinary tract; infections of the genital organs (gonorrhoea, secretion of mucus); gynaecological infections; infections of the skin and soft tissues (boils, abscesses, etc.). **Posology and Method of Administration: Usual dosage:** Augmentin is best taken at the start of a meal, with at least half a glass of water. This will ensure optimal action and tolerability. Unless prescribed otherwise by the doctor, the dosage is as follows: *Adults with mild, moderate and severe infections:* 2 x daily Augmentin 1 g (875/125). **Contraindications:** You should not take Augmentin if you had an allergic reaction previously to Augmentin, penicillin or cephalosporin. An allergy or hypersensitivity manifests as symptoms such as red spots on the skin, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. hives) and mucous membranes, skin rashes or a painful tongue. In cases of known or suspected hypersensitivity to any of the other ingredients of the medicine, Augmentin must not be used. You must not take Augmentin if you have mononucleosis or lymphocytic leukaemia. **Warnings and Precautions:** This medicine has been prescribed for you by your doctor to treat your current disease. The antibiotic in Augmentin is not effective against all micro-organisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it for the treatment of other diseases or other people. You must also not use it for subsequent new infections without consulting a doctor. The signs of illness often disappear before the infection has been completely cured. This means that the treatment must not be interrupted early, even if you feel better. Depending on the circumstances and as instructed by the doctor, the treatment may last up to two weeks or longer. This medicine may affect responsiveness and the ability to drive and use tools or machines. If you are taking an oral contraceptive (the pill), its efficacy may be reduced during antibiotic therapy. Therefore, your doctor or pharmacist can recommend additional contraceptive measures. Indigestion may occur during the use of Augmentin. In severe gastrointestinal disturbances, with vomiting and diarrhoea, the medicine should be stopped and the doctor should be seen immediately. A doctor should also be contacted if a skin rash or itching appears. If diarrhoea occurs, no medicine that inhibits intestinal peristalsis (intestinal motility) must be taken. If you have allergies, allergic asthma, hay fever or hives, special caution is advised when using Augmentin due to possible hypersensitivity reactions. Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric) are more prone to rashes. Check with your doctor if you have a kidney function disorder; he/she will prescribe a dosage tailored to fit your needs. Check with your doctor if you are using blood thinners (anticoagulants). Check with your doctor if you are using mycophenolate mofetil-containing medicines given following organ transplants as prophylaxis for acute graft rejection reactions. If you are taking medicines containing digoxin, you must inform your doctor or pharmacist. Extreme caution is required in cases of decreased kidney or liver function. Check with your doctor or pharmacist if you have other diseases, have allergies or are taking or applying other medicines (including over-the-counter drugs) externally. **Pregnancy:** The use of medicines of any kind should be decided during pregnancy with the greatest caution and only after consulting your doctor or pharmacist. **Breast-feeding:** There is a possibility of a hypersensitivity reaction (with symptoms such as rash and fever) or diarrhoea in the infant. Therefore, Augmentin should not be taken during breast-feeding or should be stopped. **Possible side effects:** Gastrointestinal disorders such as stomach discomfort or queasiness. Reactions such as nausea, loss of appetite, bloating, vomiting, diarrhoea, loose stools, dyspepsia, abdominal pain and inflammation of the tongue or oral mucosa may also occur. Gastrointestinal symptoms are less common when Augmentin is taken at the start of a meal. Allergic reactions are common with Augmentin, as with all medicines in the group of penicillins. Rashes, redness, itching and urticaria (hives) may occur. Fungal infections of the skin/mucous membranes may also occur. Dizziness and headaches can sometimes occur. See your doctor immediately if the following occur: Hives, skin rash over large areas of the skin reddening of the skin; the yellowish colour of the skin or white part of the eyes; sudden onset of stomach pain or vomiting; severe, bloody or persistent diarrhoea; breathing problems in the form of asthma attacks and hay fever If you notice side effects not described here, you must inform your doctor or pharmacist. 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. **PHARMACEUTICAL DATA: List of Excipients:** Colloidal silicon dioxide, sodium starch glycolate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicon oil). **Contents of the pack:** Available in pharmacies against a doctor's prescription that may only be filled once. Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets. **Special Precautions for Storage:** Store in a dry place at or below 30°C. Store in the original package in order to protect from moisture. Tablets in desiccated pouch packs should be used within 14 days of opening. If you notice any discolouration of the Augmentin film-coated tablets, there may have been a change in the medicine. If this happens, see your doctor or pharmacist immediately. Do not use this medicine after the expiry date which is stated on the pack after "EXP". **Manufactured by:** SmithKline Beecham Limited* Worthing, United Kingdom **This leaflet was last revised in June 2015.** Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: June 2015.

**Prescribing Information for Qatar
Augmentin 156 mg/5 ml Suspension**

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid.

Each ml of suspension contains amoxicillin trihydrate equivalent to 25 mg amoxicillin and potassium clavulanate equivalent to 6.25 mg of clavulanic acid.

PHARMACEUTICAL FORM

Augmentin 156 mg/5 ml Suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and 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.

Augmentin is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections

Posology and Method of Administration

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for reconstitution

Remove cap and check foil-backed bottle seal is intact before using. Shake the bottle to loosen the powder and remove the foil-backed seal. Add the volume of water (as indicated below), close, invert, and shake well.

Alternatively, shake the bottle to loosen the powder then fill the bottle with water to just below the line on the label. Close, invert and shake well, then top up with water exactly to the line. Close, invert, and again shake well.

<u>Strength</u>	<u>Volume of water to be added at reconstitution (ml)</u>	<u>Final volume of reconstituted oral suspension (ml)</u>
125 mg/31.25 mg/5 ml	92	100

Shake the bottle well before each dose.

Adults and children weighing 40 kg or 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 worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. You should use this to give the correct dose to your baby or child.
- Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Augmentin

- Always shake the bottle well before each dose
- Give with a meal
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Augmentin

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

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

Advice/medical education

Antibiotics are used to treat infections caused by bacteria.

They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons.

Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 156 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

Content Lab Code: PI-6709

Date of Preparation: September 2020

1. It is very important that you take the antibiotic at the right dose, at the right times, and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotics left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

Contraindications

Do not give your child Augmentin:

- if they are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine.
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not give Augmentin to your child if any of the above apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Augmentin.

Warnings and Precautions

Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin.

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 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.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with a condition called 'phenylketonuria'.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

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

If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin.

If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed.

Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility

If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse.

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

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever.

Contact your doctor as soon as possible for advice if your child gets these symptoms

Very common side effects

These may affect more than 1 in 10 people

- diarrhea (in adults).

Common side effects

- These may affect up to 1 in 10 people
- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses

If affected take Augmentin with a meal

- vomiting
- diarrhea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 156 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

Content Lab Code: PI-6709

Date of Preparation: September 2020

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- 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 - *erythema multiforme*) if you notice any of these symptoms contact a doctor urgently.

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 available data.

- Allergic reactions
- Inflammation of the large intestine
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis*)

- widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)

- a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).

- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Contact a doctor immediately if your child gets any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually 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 urine.

Reporting 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.

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PHARMACEUTICAL DATA

List of Excipients

Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange, and golden syrup dry flavors.

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.

Store in a dry place at 30°C or below.

Before reconstitution, keep tightly closed and store in a dry place at 30°C or below.

Once reconstituted, store in a refrigerator and use within 7 days.

Do not freeze.

Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

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 you to protect the environment.

Manufactured by:

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France

This leaflet was approved on 03/07/2018.

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QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 25 mg amoxicillin and potassium clavulanate equivalent to 6.25 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 156 mg/5 ml Suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension **CLINICAL PARTICULARS:**

Therapeutic Indications: Augmentin is an antibiotic and 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. Augmentin is used in babies and children to treat the following infections: middle ear and sinus infections, respiratory tract infections, urinary tract infections, and skin and soft tissue infections including dental infections bone and joint infections. **Posology and Method of Administration: Adults and children weighing 40 kg or 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:** Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses. **How to give Augmentin:** Always shake the bottle well before each dose. Give with a meal Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor. **If you give more Augmentin than you should:** If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. **If you forget to give Augmentin:** If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose. If your child stops taking Augmentin Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. **Contraindications: Do not give your child Augmentin:** if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine. If they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat. If they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. **Do not give Augmentin to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Augmentin **Warnings and Precautions:** Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they: have glandular fever or are being treated for liver or kidney problems or are not passing water regularly. If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin. 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. **Blood and urine tests:** If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests. Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'. Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product. **Interactions:** Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction. If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin. If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed. Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works. **Pregnancy, breast-feeding and fertility:** If your child who is about to take this medicine is pregnant or breast-feeding, or think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Driving and using machines:** Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine. **Conditions you need to look out for Allergic reactions:** Skin rash inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body fever, joint pain, swollen glands in the neck, armpit or groin swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing collapse. **Contact a doctor immediately:** If your child gets any of these symptoms, **stop taking Augmentin. Inflammation of large intestine:** Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain and/or fever. **Common side effects:** Diarrhoea (in adults), thrush (*candida* - a yeast infection of the vagina, mouth or skin folds), feeling sick (nausea), especially when taking high doses, vomiting, diarrhoea (in children). If affected, take Augmentin with a meal. **Contact a doctor immediately if your child gets any of these symptoms:** Inflammation of the liver (*hepatitis*), jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow, inflammation of tubes in the kidney, blood takes longer to clot, hyperactivity convulsions (in people taking high doses of Augmentin or who have kidney problems), black tongue which looks hairy, stained teeth (in children), usually 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 (*haemolytic anaemia*), crystals in urine. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. **PHARMACEUTICAL DATA: List of Excipients:** List of Excipients: Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange and golden syrup dry flavours. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, store in a refrigerator and use within 7 days. Do not freeze. Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month. 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 you to protect the environment. **Manufactured by: Manufacturer:** Glaxo Wellcome Production, 53100 MAYENNE, France. This leaflet was approved on 03/07/2018. Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 03 July 2018.

Prescribing Information for Qatar
Augmentin 228 mg/5 ml Suspension
Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid.

Each ml of suspension contains amoxicillin trihydrate equivalent to 40 mg and potassium clavulanate equivalent to 5.7 mg of clavulanic acid.

PHARMACEUTICAL FORM

Augmentin 200 mg/28.5 mg/5 ml powder for oral suspension is a white to off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 70 ml of an off-white liquid mixture called a suspension.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and 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.

Augmentin is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections

Posology and Method of Administration

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for reconstitution

Check cap seal is intact before using. Shake bottle to loosen powder. Add the volume of water (as indicated below). Invert and shake well.

<u>Strength</u>	<u>Volume of water to be added at reconstitution (ml)</u>	<u>Final volume of reconstituted oral suspension (ml)</u>
200 mg/28.5 mg/5 ml	64	70

Alternatively, shake the bottle to loosen the powder then fill the bottle with water to just below the line on the bottle or label. Invert and shake well, then top up with water exactly to the line. Invert and again shake well.

Adults and children weighing 40 kg or 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 worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring cup, spoon, or syringe. Instructions on how to use the dosing syringe are provided at the end of this leaflet. You should use this to give the correct dose to your baby or child.
- Recommended dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Augmentin

- Always shake the bottle well before each dose
- Give with a meal
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Augmentin

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

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

Contraindications

Do not give your child Augmentin:

- if they are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine.
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not give Augmentin to your child if any of the above apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Augmentin.

Warnings and Precautions

Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they:

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin, 228 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

Content Lab Code: PI-6710

Date of Preparation: September 2020

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin.

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 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.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Augmentin contains aspartame and maltodextrin

- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with a condition called 'phenylketonuria'.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

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

- If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.
- If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin.
- If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed.
- Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility

If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse.

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

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever.

Contact your doctor as soon as possible for advice if your child gets these symptoms.

Common side effects

- These may affect up to 1 in 10 people
- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses if affected take Augmentin with a meal
- vomiting
- diarrhea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- 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 - *erythema multiforme*) if you notice any of these symptoms contact a doctor urgently.

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 available data.

- Allergic reactions
- Inflammation of the large intestine

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin, 228 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

Content Lab Code: PI-6710

Date of Preparation: September 2020

- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
 - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Contact a doctor immediately if your child gets any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually 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 urine.

Reporting of side effects

If your child gets side effects talk to your doctor, pharmacist, or nurse. 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.

PHARMACEUTICAL DATA

List of Excipients

List of Excipients: Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavors, aspartame.

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.

The dry powder should be stored in unopened containers in a dry place below 30°C.

Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days.

Do not freeze.

Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.

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 to protect the environment.

Advice/medical education

Antibiotics are used to treat infections caused by bacteria.

They have no effect against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them. When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times, and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotics left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

Manufactured by:

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France

This leaflet was approved on 28/02/2018.

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Abbreviated Prescribing Information for Qatar
Augmentin 228 mg/5 ml
Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 40 mg and potassium clavulanate equivalent to 5.7 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 200 mg/28.5 mg/5 ml powder for oral suspension is a white to off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 70 ml of an off-white liquid mixture called a suspension.

CLINICAL PARTICULARS: Therapeutic Indications: Augmentin is an antibiotic and 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. Augmentin is used in babies and children to treat the following infections: Middle ear and sinus infections, respiratory tract infection, urinary tract infections, and skin and soft tissue infections including dental infections bone and joint infections. **Posology and Method of Administration: Adults and children weighing 40 kg or over:** This suspension is not usually recommended for adults and children weighing 40 kg and over. **Children weighing less than 40 kg:** Recommended dose – 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses. Higher dose – up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses. **Patients with kidney and liver problems:** If your child has kidney problems the dose might be lowered. If your child has liver problems they may have more frequent blood tests to see how their liver is working. **How to give Augmentin:** Always shake the bottle well before each dose. Give with a meal. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor. **If you give more Augmentin than you should:** If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor. **If you forget to give Augmentin:** If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose. If your child stops taking Augmentin Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. **Contraindications: Do not give your child Augmentin** if they are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine or if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat. Or if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. **Do not give Augmentin to your child if any of the above apply to your child.** If you are not sure, talk to their doctor or pharmacist before giving Augmentin. **Warnings and Precautions:** Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they: have glandular fever or are being treated for liver or kidney problems or are not passing water regularly. If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin. 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 different medicine. **Conditions you need to look out for:** Augmentin can make some existing conditions worse, or cause serious side effects. 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Do not drive or operate machinery unless you are feeling well. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine. **Conditions you need to look out for Allergic reactions:** Skin rash inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body fever, joint pain, swollen glands in the neck, armpit or groin swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing collapse. **Contact a doctor immediately** if your child gets any of these symptoms. **Stop taking Augmentin. Inflammation of large intestine:** Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever. **Contact your doctor as soon as possible** for advice if your child gets these symptoms. **Common side effects:** Diarrhea (in adults), thrush (*candida* - a yeast infection of the vagina, mouth, or skin folds), feeling sick (nausea), especially when taking high doses, and vomiting. If affected, take Augmentin with a meal. **Contact a doctor immediately if your child gets any of these symptoms.** Inflammation of the liver (*hepatitis*) jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow, inflammation of tubes in the kidney blood, takes longer to clot, hyperactivity, convulsions (in people taking high doses of Augmentin or who have kidney problems), a black tongue which looks hairy, stained teeth (in children), usually 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 urine. **PHARMACEUTICAL DATA: List of Excipients:** List of Excipients: Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavors, aspartame. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days. Do not freeze. Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month. 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 you to protect the environment. **Manufactured by:** Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France **This leaflet was approved on 28/02/2018.** Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Prescribing Information for Qatar
Augmentin 312 mg/5 ml Suspension
Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 50 mg amoxicillin and potassium clavulanate equivalent to 12.5 mg of clavulanic acid.

PHARMACEUTICAL FORM

Augmentin 312 mg/5 ml Suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and 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.

Augmentin is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections

Posology and Method of Administration

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for reconstitution

Check cap seal is intact before using. Shake bottle to loosen powder. Add the volume of water (as indicated below) invert and shake well. Alternatively, shake the bottle to loosen the powder then fill the bottle with water to just below the line on the bottle or label. Invert and shake well, then top up with water exactly to the line. Invert and again shake well.

Strength	Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral the suspension (ml)
250 mg/62.5mg/5 ml	90	100

Shake the bottle well before each dose.

Adults and children weighing 40 kg or 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 worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a plastic measuring cup, spoon, or syringe. Instructions on how to use the dosing syringe are provided at the end of this leaflet. You should use this to give the correct dose to your baby or child.
- Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Augmentin

- Always shake the bottle well before each dose
- Give with a meal
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Augmentin

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses. Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them. When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose, at the right times, and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 312 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

Content Lab Code: PI-6711

Date of Preparation: September 2020

4. You should not give antibiotics that were prescribed for you to other people.

5. If you have any antibiotics left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

Contraindications

Do not give your child Augmentin:

- if they are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine.
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not give Augmentin to your child if any of the above

apply to your child. If you are not sure, talk to their doctor or pharmacist before giving Augmentin

Warnings and Precautions

Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

If you are not sure if any of the above apply to your child, talk to their doctor or pharmacist before giving Augmentin.

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 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.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with a condition called 'phenylketonuria'.
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

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

- If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.
- If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin.
- If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed.

Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, breast-feeding and fertility

If your child who is about to take this medicine is pregnant or breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse.

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

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever.

Contact your doctor as soon as possible for advice if your child gets these symptoms

Very common side effects

These may affect more than 1 in 10 people

- diarrhea (in adults).

Common side effects

- These may affect up to 1 in 10 people
- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses if affected take Augmentin with a meal
- vomiting
- diarrhea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 312 mg/5 ml Suspension

Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

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Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- 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 - *erythema multiforme*) if you notice any of these symptoms contact a doctor urgently.

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 available data.

- Allergic reactions
- Inflammation of the large intestine
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - *toxic epidermal necrolysis*)

- widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)

- a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).

- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Contact a doctor immediately if your child gets any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually 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 urine.

Reporting of side effects

If your child gets side effects talk to your doctor, pharmacist, or nurse. 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.

PHARMACEUTICAL DATA

List of Excipients

Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange, and golden syrup dry flavors.

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.

Store in a dry place at 30°C or below.

Before reconstitution, keep tightly closed and store in a dry place at 30°C or below.

Once reconstituted, store in a refrigerator and use within 7 days.

Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 you to protect the environment.

Manufactured by:

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France

This leaflet was approved on 27/04/2018.

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Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com.

Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 27 April 2018.

Abbreviated Prescribing Information for Qatar
Augmentin 312 mg/5 ml Suspension
Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 50 mg amoxicillin and potassium clavulanate equivalent to 12.5 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 312 mg/5 ml Suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension. **CLINICAL PARTICULARS:**

Therapeutic Indications: Augmentin is an antibiotic and 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. Augmentin is used in babies and children to treat the following infections: middle ear and sinus infections, respiratory tract infections, urinary tract infections, and skin and soft tissue infections including dental infections, and bone and joint infections. **Posology and Method of Administration: Adults and children weighing 40 kg or over:** This suspension is not usually recommended for adults and children weighing 40 kg and over. **Children weighing less than 40 kg:** Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses. **How to give Augmentin:** Always shake the bottle well before each dose. Give with a meal. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor. **If you give more Augmentin than you should:** If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. **If you forget to give Augmentin** If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose. **If your child stops taking Augmentin** Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back. **Contraindications: Do not give your child Augmentin:** if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat. If they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. **Do not give Augmentin to your child if any of the above apply to your child. Warnings and Precautions:** Check with their doctor, pharmacist, or nurse before giving your child Augmentin if they have glandular fever, or are being treated for liver or kidney problems, or are not passing water regularly. 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 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. **Blood and urine tests:** If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Augmentin. This is because Augmentin can affect the results of these types of tests. Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with a condition called 'phenylketonuria'. Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product. **Interactions:** Tell your doctor or pharmacist if your child is taking, has recently taken, or might take any other medicines. If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction. If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin. If medicines to help stop blood clots (such as warfarin) are taken with Augmentin then extra blood tests may be needed. Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Augmentin may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works. **Pregnancy, breast-feeding and fertility:** If your child who is about to take this medicine is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Driving and using machines:** Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine. **Conditions you need to look out for Allergic reactions:** skin rash inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body fever, joint pain, swollen glands in the neck, armpit or groin swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing collapse. **Contact a doctor immediately** if your child gets any of these symptoms. **Stop taking Augmentin. Inflammation of large intestine** Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever. **Contact your doctor as soon as possible** for advice if your child gets these symptoms. **Very common side effects:** Diarrhea (in adults), thrush (*candida* - a yeast infection of the vagina, mouth or skin folds), feeling sick (nausea), especially when taking high doses if affected take Augmentin with a meal vomiting diarrhea (in children). **Contact a doctor immediately if your child gets any of these symptoms.** inflammation of the liver (*hepatitis*) jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow, inflammation of tubes in the kidney, blood takes longer to clot, hyperactivity, convulsions (in people taking high doses of Augmentin or who have kidney problems), black tongue which looks hairy stained teeth (in children), usually 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 urine. **PHARMACEUTICAL DATA: List of Excipients:** Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange, and golden syrup dry flavors. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, store in a refrigerator and use within 7 days. Do not freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. 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 you to protect the environment. **Manufactured by:** Glaxo Wellcome Production, 53100 MAYENNE, France **This leaflet was approved on 27/04/2018.** Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 27 April 2018.

Prescribing Information for Qatar
Augmentin 457 mg/5 ml Suspension
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Augmentin contains the active ingredients amoxicillin (as amoxicillin trihydrate) and clavulanic acid (as potassium salt).

5 mL suspension contains:	Amoxicillin	Clavulanic acid	The ratio of amoxicillin to clavulanic acid
Augmentin 457 mg/5 mL (400/57)	400 mg	57 mg	7: 1

PHARMACEUTICAL FORM

Clear, glass bottles, containing an off-white dry powder.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic from the group of penicillins. It consists of two active ingredients: clavulanic acid and amoxicillin.

Clavulanic acid controls the major defence or resistance mechanism of numerous bacteria resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This mode of action makes Augmentin effective against numerous bacterial infections. Augmentin may be used only when prescribed by a doctor for the exclusive treatment of the following bacterial infections:

- Nose, throat, tonsil, front/maxillary sinus and ear infections;
- Respiratory tract infections (bronchi and lungs).

Posology and Method of Administration

Posology/Use

Augmentin should preferably be taken at the start of meals. In this way, optimum efficacy and tolerance are achieved.

Children:

The doctor determines the dose based on the child's body weight and the severity of the infection. Follow the prescribed dosage exactly.

Augmentin 457 mg/5 mL (400/57) suspension is used for certain infections in children aged 2 months and older and must be taken 2 times daily.

Dose recommendations

Unless otherwise prescribed by your doctor the following dose recommendations apply:

For the treatment of infections in newborn and breast-fed infants up to the age of 3 months, parenteral Augmentin is indicated. Please ask your doctor.

Augmentin 457 mg/5 mL:

Augmentin is used to treat certain infections in children starting at the age of 2 months and older.

Tonsillitis and Infections of the lower respiratory tract:

Weight	Approximate age	Dose Augmentin 457 mg/5 mL (400/57) suspension
13 – 15 kg	2 – 3 years	2 times daily 2.5 mL
16 – 18 kg	3 – 5 years	2 times daily 3 mL
19 – 21 kg	5 – 6 years	2 times daily 3.5 mL
22 – 30 kg	6 – 10 years	2 times daily 5 mL
31 – 40 kg	10 – 12 years	2 times daily 7.5 mL

Middle ear inflammation:

Weight	Approximate age	Dose Augmentin 457 mg/5 mL (400/57) suspension
4 – 6 kg	2 – 6 months	2 times daily 1 mL
7 – 9 kg	6 – 12 months	2 times daily 1.6 mL
10 – 12 kg	1 – 2 years	2 times daily 2 mL
13 – 17 kg	2 – 4 years	2 times daily 5 mL
18 – 26 kg	4 – 8 years	2 times daily 7.5 mL
27 – 35 kg	8 – 10 years	2 times daily 10 mL
36 – 40 kg	10 – 12 years	2 times daily 12.5 mL

An initiated antibiotics therapy should be continued for as long as prescribed by the doctor.

The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, do not discontinue the therapy prematurely.

Do not change the prescribed dosage on your own. If you think that the medicine is too weak or too strong talk to your doctor or pharmacist.

Instructions for reconstitution

Normally, the suspensions are prepared by the pharmacist. If the suspension is not prepared, tap water must be added to the powder as follows:

Augmentin 457 mg/5 mL (400/57) suspension

Shake the bottle with the powder. Carefully fill with tap water (in 2 portions) to the line on the label (62 mL for 70 mL of suspension). Shake the bottle well and let sit for a short time. If necessary, add water again up to the line. This makes a 70 mL ready-for-use suspension. Shake the bottle before each use. 2.5 mL = 228.5 mg active ingredients (200 mg amoxicillin, 28.5 mg clavulanic acid). 5 mL = 457 mg active ingredients (400 mg amoxicillin, 57 mg clavulanic acid).

The suspension should only be prepared immediately before use. If you are not comfortable preparing the suspension yourself, have Augmentin prepared in your pharmacy.

Contraindications

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 457 mg/5 ml Suspension

Amoxicillin trihydrate + Potassium clavulanate

Content Lab Code: PI-6712

Date of Preparation: September 2020

Do not take Augmentin:

Patients who have previously had an allergic reaction to Augmentin, penicillins or cephalosporins should not take Augmentin. An allergy or hypersensitivity manifests itself e.g. in symptoms such as red skin blotches, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. nettle rash) and the mucous membranes, skin rash or a painful tongue.

Augmentin must not be used in case of known or suspected hypersensitivity to one of the other ingredients of the medicine.

Patients with infectious mononucleosis or lymphatic leukaemia must not take Augmentin.

Warnings and Precautions

This medicine may impair your ability to react, drive and use tools or machines.

If the patient takes an oral contraceptive (the pill) its effectiveness may be reduced while taking antibiotics. This also applies to Augmentin. Your doctor or pharmacist may therefore recommend additional contraceptive measures.

Digestive disorders are possible when taking Augmentin. In case of severe gastrointestinal disorders accompanied by vomiting and diarrhoea, the medicine should be discontinued and the doctor contacted immediately. He/she should also be informed if a rash or pruritus occurs.

In the case of diarrhoea, medicines that inhibit bowel peristalsis (bowel motility) must not be taken.

Isolated cases of particularly severe allergic reactions such as (potentially life-threatening) drug rash with eosinophilia and systemic symptoms (DRESS) have been reported after taking Augmentin.

Signs of such skin reactions include:

- Influenza-like symptoms with rash and fever;
- Skin rash;
- Swelling of the face or other body parts.

If you detect such symptoms in yourself after taking Augmentin, you must immediately stop the treatment and contact a doctor.

For patients with phenylketonuria: the suspensions are sweetened with aspartame.

Before you take Augmentin

This medicine was prescribed for you by your doctor for the treatment of the present disorder.

The antibiotic in Augmentin is not effective against all microorganisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it on your own for the treatment of other disorders or other people. Even in the case of later occurring new infections, you must not use Augmentin without seeing a doctor again.

The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, treatment must not be discontinued prematurely even if you feel better.

Depending on the circumstances, and subject to the doctor's instruction, the treatment may last up to two weeks or longer.

Interactions

Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric®) are more prone to rashes.

Inform your doctor if you have a renal function disorder.

Inform your doctor if you are taking blood thinners (anticoagulants) concomitantly.

Inform your doctor if you are taking mycophenolate-mofetil-containing medicines that are used after organ transplant as prophylaxis against acute transplant rejection reactions.

You must notify your doctor or pharmacist if you or your child take digoxin-containing medicines.

Special caution is advised in case of insufficient kidney or liver function.

Inform your doctor or pharmacist if you or your child

- are suffering from any other diseases,
- have allergies or
- are taking any other medications (even those you bought yourself) or are applying them externally

Pregnancy and breast-feeding

The suspensions are intended for children. If you have questions concerning pregnancy and breastfeeding contact your doctor or pharmacist. The use of any type of medicine during pregnancy should be decided with the greatest caution and only after consultation with your doctor or pharmacist. It has been reported in studies on pregnant women with premature rupture of membranes (amniorrhesis) that prophylactic treatment with Augmentin may increase the risk of partially severe intestinal inflammation involving tissue damage in newborn infants.

Breast-feeding

As Augmentin is excreted in small amounts in human milk the possibility of a hypersensitivity reaction (involving symptoms such as reddening of the skin and fever) or diarrhoea should be expected for breastfed infants. Therefore, Augmentin should not be used during breast-feeding or breast-feeding should be discontinued.

Possible side effects

Gastrointestinal disorders such as stomach discomfort or nausea. Likewise, reactions such as vomiting, retching, loss of appetite, bloating, diarrhoea, soft stools, dyspepsia, bellyache and inflammation of the tongue and oral mucosa may occur.

If Augmentin is taken at the start of meals, gastrointestinal discomfort is less common.

As with all medicines of the penicillin group, allergic reactions with Augmentin are common.

Skin rash, reddening of the skin, pruritus and urticaria (nettle rash) may occur.

Likewise, fungal infections of the skin/mucous membranes may occur.

Dizziness and headaches are uncommon.

Very rarely, hyperactivity, excitation, anxiety, sleeplessness, confusion, changes in behaviour, giddiness, cramps and sensory disorders may occur.

Rarely, especially after taking the suspension, superficial tooth discolourations have been observed. This discolouration usually disappears again when brushing teeth.

Very rarely, a dark-coated tongue, hyperkinesia (excessive movement activity), changes in blood count, prolonged bleeding and prothrombin time, inflammation of the liver (hepatitis), inflammation of the kidneys and renal function disorders have been observed.

Very rarely, influenza-like symptoms have been observed such as skin rash, fever, swollen glands and abnormal blood counts (including white blood cells [eosinophilia] and liver enzymes) (drug rash with eosinophilia and systemic systems [DRESS]).

When administering amoxicillin at the ages of 0 – 9 months, damage to the tooth enamel (e.g. white striping, discolouration) of the definitive incisors cannot be excluded.

Jaundice has been reported rarely.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 457 mg/5 ml Suspension

Amoxicillin trihydrate + Potassium clavulanate

Content Lab Code: PI-6712

Date of Preparation: September 2020

Consult your doctor immediately if the following occur:

- Nettle rash, skin rash over large areas of the skin, reddening of the skin;
- Yellowish colour of the skin or white part of the eyes;
- Sudden onset of belly ache or vomiting;
- Severe, bloody or persistent diarrhoea;
- Breathing problems in the form of asthma attacks and hay fever.

Inform your doctor or pharmacist if you notice side effects that are not described here.

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.

PHARMACEUTICAL DATA

List of Excipients

Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavours, aspartame.

Special Precautions for Storage

The dry powder should be stored in unopened containers in a dry place at below 30°C.

Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days.

Do not freeze.

If you notice a discolouration of the Augmentin suspensions, this could indicate that the preparation has changed. If this occurs contact your doctor or pharmacist immediately.

Following the completion of treatment, the remaining medicine should be returned to where you obtained it (doctor or pharmacist) for proper disposal.

Do not use this medicine after the expiry date ("EXP") which is stated on the container.

The doctor or the pharmacist can provide additional information. They have a detailed summary of product characteristics.

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France

This leaflet was last revised in January 2018.

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Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: January 2018.

Abbreviated Prescribing Information for Qatar
Augmentin 457 mg/5 ml Suspension
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Augmentin contains 400 mg amoxicillin (as amoxicillin trihydrate) and 57 mg clavulanic acid (as potassium salt).

PHARMACEUTICAL FORM: Clear, glass bottles, containing an off-white dry powder. **CLINICAL PARTICULARS:** **Therapeutic Indications:** Augmentin is an antibiotic from the group of penicillins. Clavulanic acid controls the major defence or resistance mechanism of numerous bacteria resistant to penicillins and in this way protects amoxicillin so that it can destroy the bacteria. This mode of action makes Augmentin effective against numerous bacterial infections. Augmentin may be used only when prescribed by a doctor for the exclusive treatment of the following bacterial infections: Nose, throat, tonsil, front/maxillary sinus and ear infections; respiratory tract infections (bronchi and lungs); **Posology and Method of Administration:** Augmentin should preferably be taken at the start of meals. In this way, optimum efficacy and tolerance are achieved. Children: The doctor determines the dose based on the child's body weight and the severity of the infection. Follow the prescribed dosage exactly. Augmentin 457 mg/5 mL (400/57) suspension is used for certain infections in children aged 2 months and older and must be taken 2 times daily. **Augmentin 457 mg/5 ml:** Augmentin is used to treat certain infections in children starting at the age of 2 months and older. Tonsillitis and Infections of the lower respiratory tract: Middle ear inflammation: The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, do not discontinue the therapy prematurely. Do not change the prescribed dosage on your own. If you think that the medicine is too weak or too strong talk to your doctor or pharmacist. The antibiotic in Augmentin is not effective against all microorganisms that cause infectious diseases. Using the wrong antibiotic or the wrong dose of the antibiotic can cause complications. Therefore, never use it on your own for the treatment of other disorders or other people. Even in the case of later occurring new infections, you must not use Augmentin without seeing a doctor again. The symptoms of the disease and the feeling of sickness frequently disappear before the infection is completely healed. Therefore, treatment must not be discontinued prematurely even if you feel better. Depending on the circumstances, and subject to the doctor's instruction, the treatment may last up to two weeks or longer. **Contraindications Do not take Augmentin:** Patients who have previously had an allergic reaction to Augmentin, penicillins or cephalosporins should not take Augmentin. An allergy or hypersensitivity manifests itself e.g. in symptoms such as red skin blotches, fever, asthma, respiratory distress, circulatory problems, swelling of the skin (e.g. nettle rash) and the mucous membranes, skin rash or a painful tongue. Augmentin must not be used in case of known or suspected hypersensitivity to one of the other ingredients of the medicine. Patients with infectious mononucleosis or lymphatic leukaemia must not take Augmentin. **Warnings and Precautions:** This medicine may impair your ability to react, drive and use tools or machines. If the patient takes an oral contraceptive (the pill) its effectiveness may be reduced while taking antibiotics. This also applies to Augmentin. Your doctor or pharmacist may therefore recommend additional contraceptive measures. Digestive disorders are possible when taking Augmentin. In case of severe gastrointestinal disorders accompanied by vomiting and diarrhoea, the medicine should be discontinued and the doctor contacted immediately. He/she should also be informed if a rash or pruritus occurs. In the case of diarrhoea, medicines that inhibit bowel peristalsis (bowel motility) must not be taken. Isolated cases of particularly severe allergic reactions such as (potentially life-threatening) drug rash with eosinophilia and systemic symptoms (DRESS) have been reported after taking Augmentin. **Signs of such skin reactions include** Influenza-like symptoms with rash and fever; skin rash; and swelling of the face or other body parts. For patients with phenylketonuria, the suspensions are sweetened with aspartame. **Interactions:** Patients who need to take allopurinol-containing medicines at the same time (e.g. Zyloric®) are more prone to rashes. Inform your doctor if you have a renal function disorder. Inform your doctor if you are taking blood thinners (anticoagulants) concomitantly. Inform your doctor if you are taking mycophenolate-mofetil-containing medicines that are used after organ transplant as prophylaxis against acute transplant rejection reactions. You must notify your doctor or pharmacist if you or your child take digoxin-containing medicines. Special caution is advised in case of insufficient kidney or liver function. Inform your doctor or pharmacist if you or your child - are suffering from any other diseases, - have allergies or - are taking any other medications (even those you bought yourself) or are applying them externally. **Pregnancy and breast-feeding:** The suspensions are intended for children. If you have questions concerning pregnancy and breastfeeding contact your doctor or pharmacist. The use of any type of medicine during pregnancy should be decided with the greatest caution and only after consultation with your doctor or pharmacist. It has been reported in studies on pregnant women with premature rupture of membranes (amniorrhesis) that prophylactic treatment with Augmentin may increase the risk of partially severe intestinal inflammation involving tissue damage in newborn infants. **Breast-feeding:** Augmentin should not be used during breast-feeding or breast-feeding should be discontinued. **Possible side effects:** Gastrointestinal disorders such as stomach discomfort or nausea. Likewise, reactions such as vomiting, retching, loss of appetite, bloating, diarrhoea, soft stools, dyspepsia, bellyache and inflammation of the tongue and oral mucosa may occur. If Augmentin is taken at the start of meals, gastrointestinal discomfort is less common. As with all medicines of the penicillin group, allergic reactions with Augmentin are common. Skin rash, reddening of the skin, pruritus and urticaria (nettle rash) may occur. Likewise, fungal infections of the skin/mucous membranes may occur. When administering amoxicillin at the ages of 0 – 9 months, damage to the tooth enamel (e.g. white striping, discolouration) of the definitive incisors cannot be excluded. Consult your doctor immediately if the following occur: Nettle rash, skin rash over large areas of the skin, reddening of the skin; a yellowish colour of the skin or white part of the eyes; sudden onset of belly ache or vomiting; severe, bloody or persistent diarrhoea; breathing problems in the form of asthma attacks and hay fever. Inform your doctor or pharmacist if you notice side effects that are not described here. **PHARMACEUTICAL DATA: List of Excipients:** Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavours, aspartame. **Special Precautions for Storage:** The dry powder should be stored in unopened containers in a dry place at below 30°C. Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days. Do not freeze. If you notice a discolouration of the Augmentin suspensions, this could indicate that the preparation has changed. If this occurs contact your doctor or pharmacist immediately. Following the completion of treatment, the remaining medicine should be returned to where you obtained it (doctor or pharmacist) for proper disposal. Do not use this medicine after the expiry date ("EXP") which is stated on the container. **Manufacturer:** Glaxo Wellcome Production, 53100 MAYENNE, France. **This leaflet was last revised in January 2018. Trademarks are owned by or licensed to the GSK group of companies.** © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: January 2018.

Prescribing Information for Qatar
Augmentin™ 625 Tablets
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

AUGMENTIN 625 mg tablets: Each tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

PHARMACEUTICAL FORM

AUGMENTIN 625 mg tablets: A white to off-white oval-shaped film-coated debossed tablet, with a scoreline and AC on one side and plain on the other side.

CLINICAL PARTICULARS

Indications

AUGMENTIN is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The β -lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other β -lactam antibiotics.

AUGMENTIN oral presentations for three times daily dosing are indicated for short-term treatment of bacterial infections at the following sites:

Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media.

Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis and bronchopneumonia.

Genito-urinary tract and Abdominal infections e.g. cystitis (especially when recurrent or complicated - excluding prostatitis), urethritis, pyelonephritis.

Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections.

Dental infections e.g. dentoalveolar abscess.

Other infections e.g. intra-abdominal sepsis.

Dosage and Administration

Usual dosages for the treatment of infection

Adults and children over 12 years	
Severe infections	One <i>AUGMENTIN</i> 625 mg tablet three times a day. Therapy can be started parenterally and continued with an oral preparation.

AUGMENTIN 625 mg tablets are not recommended in children of 12 years and under.

Dosage in renal impairment

Adults:

Mild impairment (Creatinine clearance >30 ml/min)	Moderate impairment (Creatinine clearance 10-30 ml/min)	Severe impairment (Creatinine clearance <10 ml/min)
No change in dosage.	One 625 mg tablet 12 hourly	625 mg tablets are not recommended.

Children:

Similar reductions in dosage should be made for children in proportion to the recommendation for adults.

Dosage in hepatic impairment

Dose with caution; monitor hepatic function at regular intervals. There are, as yet, insufficient data on which to base a dosage recommendation.

Administration

To minimise potential gastrointestinal intolerance, administer at the start of a meal. The absorption of *AUGMENTIN* is optimised when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

Contraindications

AUGMENTIN is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins.

AUGMENTIN is contraindicated in patients with a previous history of amoxicillin-clavulanate associated jaundice/hepatic dysfunction.

Warnings and Precautions

-Before initiating therapy with *AUGMENTIN*, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens.

-Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy.

-These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity.

-*AUGMENTIN* should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

-Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

-Prolongation of prothrombin time has been reported rarely in patients receiving *AUGMENTIN*. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

-Changes in liver function tests have been observed in some patients receiving *AUGMENTIN*. The clinical significance of these changes is uncertain but *AUGMENTIN* should be used with caution in patients with evidence of hepatic dysfunction.

-Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.

-In patients with renal impairment, *AUGMENTIN* dosage should be adjusted.

-In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy.

-During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria.

-*AUGMENTIN* suspensions contain 12.5 mg aspartame per 5 ml dose, which is a source of phenylalanine, and therefore should be used with caution in patients with phenylketonuria.

Interactions

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin.

Concomitant use with *AUGMENTIN* may result in increased and prolonged blood levels of amoxicillin but not of clavulanate.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin™ 625 Tablets

Amoxicillin trihydrate + Potassium clavulanate

Content Lab Code: PI-6713

Date of Preparation: September 2020

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of *AUGMENTIN* and allopurinol.

In common with other antibiotics, *AUGMENTIN* may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Pregnancy and Lactation

In a single study in women with preterm, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with *AUGMENTIN* may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

AUGMENTIN may be administered during the period of lactation.

Effects on Ability to Drive and Use Machines

Adverse effects on the ability to drive or operate machinery have not been observed.

Adverse Reactions:

Very common >1/10:

Diarrhoea in adults.

Common >1/100 and <1/10:

Mucocutaneous candidiasis, diarrhoea in children, nausea and vomiting.

Uncommon >1/1000 and <1/100 :

Dizziness, headache, skin rash and urticaria. A moderate rise in AST and/or ALT has been noted.

Rare >1/10,000 and <1/1000:

Leucopenia (including neutropenia) and thrombocytopenia. Erythema multiforme.

Very rare <1/10,000:

-Interstitial nephritis, crystalluria, agranulocytosis and haemolytic anaemia, angioneurotic oedema, anaphylaxis, serum sickness-like syndrome and hypersensitivity vasculitis.

-Convulsions may occur in patients with impaired renal function or those receiving high doses.

-Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP).

-Gastrointestinal disorders: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis), black hairy tongue, and in suspensions: superficial tooth discolouration that can usually be removed by brushing.

-Hepatobiliary disorders: Hepatitis and cholestatic jaundice. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and in extremely rare circumstances, deaths have been reported.

-Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children.

Overdose

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water-electrolyte balance.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

AUGMENTIN can be removed from the circulation by haemodialysis.

PHARMACEUTICAL PARTICULARS

List of Excipients

AUGMENTIN 625 mg tablets:

Each tablet contains magnesium stearate, sodium starch glycolate, colloidal silica, microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol and silicone oil.

Incompatibilities

None known.

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

AUGMENTIN oral presentations should be stored in a dry place at 30°C or below.

Once reconstituted, *AUGMENTIN* suspension must be stored in a refrigerator (but not frozen) and used within 7 days.

Nature and Contents of Container

AUGMENTIN 625 mg tablets: Blister packs of 20 in a carton.

Manufactured by:

SmithKline Beecham plc*

Worthing

UK

*Member of the GlaxoSmithKline group of companies

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Version number: GDS_V18

Date of issue: 26 November 2007

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Abbreviated Prescribing Information for Qatar
Augmentin™ 625 mg Tablets
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: *AUGMENTIN 625 mg tablets*: Each tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate). **PHARMACEUTICAL FORM:** *AUGMENTIN 625 mg tablets*: A white to off-white oval-shaped film-coated debossed tablet, with a scoreline and AC on one side and plain on the other side. **CLINICAL PARTICULARS: Indications:** *AUGMENTIN* is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The β -lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other β -lactam antibiotics. *AUGMENTIN* oral presentations for three times daily dosing, are indicated for short-term treatment of bacterial infections at the following sites: *Upper respiratory tract infections (including ENT)* e.g. recurrent tonsillitis, sinusitis, otitis media, *lower respiratory tract infections* e.g. acute exacerbation of chronic bronchitis and bronchopneumonia, *genito-urinary tract and abdominal infections* e.g. cystitis (especially when recurrent or complicated - excluding prostatitis), urethritis, pyelonephritis, *skin and soft tissue infections*, e.g. boils, abscesses, cellulitis, wound infections, *dental infections* e.g. dentoalveolar abscess, and *other infections* e.g. intra-abdominal sepsis. **Dosage and Administration: Usual dosages for the treatment of infection Adults and children over 12 years:** *Severe infections*: One *AUGMENTIN* 625 mg tablet three times a day. Therapy can be started parenterally and continued with an oral preparation. *Children*: The usual recommended daily dosage is 625 mg tablets are not recommended in children of 12 years and under. **Dosage in renal impairment Adults:** *Moderate impairment (Creatinine clearance 10-30 ml/min)*: One 625 mg tablet 12 hourly. *Severe impairment (Creatinine clearance <10 ml/min)*: 625 mg tablets are not recommended. **Administration:** To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of *AUGMENTIN* is optimised when taken at the start of a meal. Treatment should not be extended beyond 14 days without review. **Contraindications:** *AUGMENTIN* is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins. *AUGMENTIN* is contraindicated in patients with a previous history of amoxicillin-clavulanate associated jaundice/hepatic dysfunction. **Warnings and Precautions:** Before initiating therapy with *AUGMENTIN*, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. *AUGMENTIN* should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. Prolongation of prothrombin time has been reported rarely in patients receiving *AUGMENTIN*. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Changes in liver function tests have been observed in some patients receiving *AUGMENTIN*. The clinical significance of these changes is uncertain but *AUGMENTIN* should be used with caution in patients with evidence of hepatic dysfunction. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased. In patients with renal impairment, *AUGMENTIN* dosage should be adjusted. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria. *AUGMENTIN* suspensions contain 12.5 mg aspartame per 5 ml dose, which is a source of phenylalanine, and therefore should be used with caution in patients with phenylketonuria. **Interactions:** Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with *AUGMENTIN* may result in increased and prolonged blood levels of amoxicillin but not of clavulanate. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of *AUGMENTIN* and allopurinol. In common with other antibiotics, *AUGMENTIN* may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. **Pregnancy and Lactation** As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician. *AUGMENTIN* may be administered during the period of lactation. **Adverse Reactions: Very Common:** Diarrhoea in adults **Common:** Mucocutaneous candidiasis, diarrhea in children, nausea, and vomiting, **Overdose:** Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water-electrolyte balance. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. *AUGMENTIN* can be removed from the circulation by haemodialysis. **PHARMACEUTICAL PARTICULARS: List of Excipients:** *AUGMENTIN 625 mg tablets*: Each tablet contains magnesium stearate, sodium starch glycolate, colloidal silica, microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, and silicone oil. **Shelf Life:** The expiry date is indicated on the packaging. **Special Precautions for Storage:** *AUGMENTIN* oral presentations should be stored in a dry place at 30°C or below. Once reconstituted, *AUGMENTIN* suspension must be stored in a refrigerator (but not frozen) and used within 7 days. **Manufactured by:** SmithKline Beecham plc* Worthing UK *Member of the GlaxoSmithKline group of companies. *AUGMENTIN* is a trademark of the GlaxoSmithKline group of companies. © 2007 GlaxoSmithKline group of companies. All rights reserved. **Version number:** GDS_V18 **Date of issue:** 26 November 2007. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 26 November 2007.

Prescribing Information for Qatar
Augmentin ES
600 mg/42.9 mg/5 ml powder for oral suspension
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid. Each ml of oral suspension contains amoxicillin trihydrate equivalent to 120 mg amoxicillin and potassium clavulanate equivalent to 8.58 mg of clavulanic acid

PHARMACEUTICAL FORM

Augmentin ES 600 mg/42.9 mg/5 ml suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white mixture called a suspension.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and 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.

Augmentin is used in babies and children to treat the following infections:

- Middle ear infections
- Pulmonary infections.

Posology and Method of Administration

Use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Instructions for reconstitution

Check cap seal is intact before using. Shake bottle to loosen powder. Add the volume of water (as indicated below). Invert and shake well.

Alternatively, fill the bottle with water to just below the mark on the bottle label. Invert and shake well. Then top up with water exactly to the line. Invert the bottle and again shake well.

<u>Concentration</u>	<u>The volume of water to be added at reconstitution</u> <u>(ml)</u>	<u>The final volume of reconstituted oral suspension</u> <u>(ml)</u>
600 mg/42.9 mg/5 ml	90	100

Adults and children weighing 40 kg or over

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

Children weighing less than 40 kg

All doses are calculated using the child's body weight in kilograms.

- Your doctor will advise you how much Augmentin you should give to your baby or child.
- You may be provided with a measuring spoon or cup. You should use it to give the correct dose to your baby or child.
- Recommended dose - 90 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.

Augmentin is not recommended for children aged less than 3 months.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. Your doctor may choose a different strength or different medicine.
- If your child has liver problems they may need more frequent blood tests to see how their liver is working.

How to use Augmentin

- Always shake the bottle well before each dose.
- Give at the start of the meal or slightly before.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you use more Augmentin than you should

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, vomiting, or diarrhea) or convulsions. Talk to your doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Augmentin

If you forget to give your child a dose of Augmentin, give it as soon as you remember. You should not give the child the next dose too soon: wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stops taking Augmentin

Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause infection again (relapse).

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

Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses. Sometimes an infection caused by bacteria does not respond to treatment with an antibiotic. One of the most common reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic. Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them. When your doctor prescribes treatment with an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

1. It is very important that you take the antibiotic at the right dose for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotics left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.

Contraindications

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin ES

600 mg/42.9 mg/5 ml powder for oral suspension

Amoxicillin trihydrate + potassium clavulanate

Content Lab Code: PI-6715

Date of Preparation: September 2020

Do not give your child Augmentin:

- if they are allergic to amoxicillin, clavulanic acid, or any of the other ingredients of this medicine
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not give Augmentin to your child if any of the above apply to your child. If you are not sure talk to your doctor or pharmacist before giving Augmentin.

Warnings and Precautions

Talk to your doctor or pharmacist before giving Augmentin to your child if:

- they have glandular fever
- they are being treated for liver or kidney problems
- they are not urinating regularly.

If you are not sure if any of the above apply to your child, talk to your doctor or pharmacist before giving Augmentin.

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 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, 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.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests, let the doctor or nurse know that they are taking Augmentin, as this medicine can affect the results of these types of tests.

Important information on some Augmentin components

- Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with "phenylketonuria".
- Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

Tell your doctor or pharmacist if your child is taking, has recently taken, or might take any other medicines, including medicines obtained without a prescription or plant-based medicines.

If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout) your doctor may decide to adjust the dose of Augmentin.

If medicines to help stop blood clots (such as warfarin) are taken with Augmentin, extra blood tests may be needed.

Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Augmentin can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Pregnancy, lactation, and fertility

If your child who is about to take Augmentin is pregnant or breast-feeding, please tell your doctor or pharmacist. Talk to your doctor or pharmacist before taking any medicinal product.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for include**Allergic reactions:**

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- fainting

Contact a doctor immediately if your child gets any of these symptoms. Stop giving your child Augmentin.

Inflammation of the large intestine

Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever.

Contact your doctor as soon as possible for advice if your child gets these symptoms.

Very common side effects

These may affect **more than 1 in 10** people

- diarrhea (in adults).

Common side effects

These may affect **up to 1 in 10** people

- thrush (candida - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses

If this occurs, take Augmentin before food

- vomiting
- diarrhea (in children).

Uncommon side effects

These may affect **up to 1 in 100** people

- skin rash, itching
- *hives* (raised itchy rash)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin ES

600 mg/42.9 mg/5 ml powder for oral suspension

Amoxicillin trihydrate + potassium clavulanate

Content Lab Code: PI-6715

Date of Preparation: September 2020

Rare side effects

These may affect **up to 1 in 1000** people

- 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-*erythema multiforme*)
- If you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown.

- Allergic reactions
- Inflammation of the large intestine
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface -*toxic epidermal necrolysis*)
 - Widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - A red scaly rash with bumps under the skin and blisters (*exanthematous pustulosis*)

Contact a doctor immediately if your child gets any of these symptoms.

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your child's skin and whites of the eyes appear yellow.
- inflammation of the tubes in the kidney
- increased blood clotting time
- hyperactivity
- seizures (in people taking high doses of Augmentin or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually 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 urine.

Reporting of side effects

If your child gets any side effects, talk to their doctor or pharmacist

PHARMACEUTICAL DATA**List of Excipients**

Aspartame (E951), xanthan gum, colloidal hydrated silicon, colloidal anhydrous silica, artificial strawberry cream flavor, and water.

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.

Powder for oral suspension:

Store in the original container to protect from moisture.

Do not store above 30°C.

Do not use Augmentin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Liquid suspension:

Store in a refrigerator (2°C-8°C). Do not freeze.

Once made up, the suspension should be used within 10 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 you to protect the environment.

Manufacturer:

GlaxoWellcome Production*, Mayenne, France

***Member of the GlaxoSmithKline group of companies**

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This leaflet was last revised in 03/2015

Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com.

Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: March 2015.

Abbreviated Prescribing Information for Qatar
Augmentin ES
600 mg/42.9 mg/5 ml powder for oral suspension
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each ml of oral suspension contains amoxicillin trihydrate equivalent to 120 mg amoxicillin and potassium clavulanate equivalent to 8.58 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin ES 600 mg/42.9 mg/5 ml suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white mixture called a suspension. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is an antibiotic and 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. Augmentin is used in babies and children to treat middle ear infections and pulmonary infections. **Posology and Method of Administration: Adults and children weighing 40 kg or over:** This suspension is not usually recommended for adults and children weighing 40 kg or over. **Children weighing less than 40 kg:** Recommended dose - 90 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses. Augmentin is not recommended for children aged less than 3 months, or patients with kidney and liver problems. If your child has kidney problems, the dose might be lowered. **How to use Augmentin:** Always shake the bottle well before each dose. Give it at the start of a meal or slightly before. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor. **If you use more Augmentin than you should:** If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, vomiting, or diarrhea) or convulsions. Talk to your doctor as soon as possible. **If you forget to give Augmentin:** If you forget to give your child a dose of Augmentin, give it as soon as you remember. You should not give the child the next dose too soon: wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose. **If your child stops taking Augmentin:** Keep giving your child Augmentin until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause infection again (relapse). **Contraindications:** If they are allergic to amoxicillin, clavulanic acid, or any of the other ingredients of this medicine. If they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat. If they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. Do not give Augmentin to your child if any of the above apply to your child. **Warnings and Precautions:** Talk to your doctor or pharmacist before giving Augmentin to your child if: they have glandular fever, they are being treated for liver or kidney problems, or they are not urinating regularly. 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 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, 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. **Blood and urine tests:** If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests, let the doctor or nurse know that they are taking Augmentin, as this medicine can affect the results of these types of tests. **Important information on some Augmentin components:** Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with "phenylketonuria". Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars. **Interactions:** Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription or plant-based medicines. If your child is taking allopurinol (used for gout) with Augmentin, it may be more likely that they will have an allergic skin reaction. If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Augmentin. If medicines to help stop blood clots (such as warfarin) are taken with Augmentin, extra blood tests may be needed. Augmentin can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works. Augmentin can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works. **Pregnancy, lactation, and fertility:** If your child who is about to take Augmentin is pregnant or breast-feeding, please tell your doctor or pharmacist. **Possible side effects Allergic reactions:** skin rash, inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body fever, joint pain, swollen glands in the neck, armpit or groin swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing fainting. Contact a doctor immediately if your child gets any of these symptoms. Stop giving your child Augmentin. **Inflammation of the large intestine:** Inflammation of the large intestine, causing watery diarrhea usually with blood and mucus, stomach pain, and/or fever. Contact your doctor as soon as possible for advice if your child gets these symptoms. **Very common side effects:** diarrhea (in adults). **Common side effects:** thrush (candida - a yeast infection of the vagina, mouth or skin folds), feeling sick (nausea), especially when taking high doses, vomiting, and diarrhea (in children). If this occurs, take Augmentin before food. **PHARMACEUTICAL DATA: List of Excipients:** Aspartame (E951), xanthan gum, colloidal hydrated silicon, colloidal anhydrous silica, artificial strawberry cream flavor, and water. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. **Powder for oral suspension:** Store in the original container to protect from moisture. Do not store above 30°C. Do not use Augmentin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. **Liquid suspension:** Store in a refrigerator (2°C-8°C). Do not freeze. Once made up, the suspension should be used within 10 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 you to protect the environment. **Manufacturer: GlaxoWellcome Production*, Mayenne, France *Member of the GlaxoSmithKline group of companies.** AUGMENTIN ES and AUGMENTIN are trademarks of the GlaxoSmithKline group of companies © 2017 GSK group of companies. All rights reserved. **This leaflet was last revised in 03/2015.** Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: March 2015.

Prescribing Information for Qatar
Augmentin 62.5 mg/ml Infant Drops
Amoxicillin trihydrate + Potassium clavulanate
Powder for oral suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION

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 acid.

PHARMACEUTICAL FORM

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.

CLINICAL PARTICULARS

Therapeutic Indications

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.

Posology and Method of Administration

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 syringe, 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	The volume of water to be added to prepare (ml)	The final volume of prepared oral suspension (ml)
50 mg/12,5 mg/ml	18	20

Shake the bottle well before each use.

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 bodyweight 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. A 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 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.

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 infectious diseases 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.

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 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.

Contraindications

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 62.5 mg/ml Infant Drops

Amoxicillin trihydrate + Potassium clavulanate

Content Lab Code: PI-6714

Date of Preparation: September 2020

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.
- 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 other 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.

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 contains aspartame and maltodextrin

- Augmentin contains aspartame (E 951) as a source of phenylalanine and may be harmful to children born with a condition called phenylketonuria.
- 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.

Interactions

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 your child 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.

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:

- 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.

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

Inflammation of the large intestine

Inflammation of the large intestine that causes watery diarrhea, usually with blood and mucus, stomach pain, and / or fever.

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).

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
- Lofter 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.

Prescribing Information and Abbreviated Prescribing Information for Qatar, Augmentin 62.5 mg/ml Infant Drops

Amoxicillin trihydrate + Potassium clavulanate

Content Lab Code: PI-6714

Date of Preparation: September 2020

Rare side effects

1 to 10 people out of 10,000

- Skin rash, possibly with blisters that looks like small targets (a 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
- Inflammation of the large intestine
- 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 (*exanthemous 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.

- 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 on 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.

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.

PHARMACEUTICAL DATA**List of Excipients**

Aspartame (E 951), xanthan gum, silica, fumed silica, succinic acid, hypromellose, orange flavor 1* & 2*, raspberry flavor * and gold syrup flavor*.

* It contains maltodextrin.

Special Precautions for Storage

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 to protect the environment.

Manufacturer:

Glaxo Wellcome Production*, 53100 Mayenne, France

*member of GSK group of companies.

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Abbreviated Prescribing Information for Qatar
Augmentin 62.5 mg/ml Infant Drops
Amoxicillin trihydrate + Potassium clavulanate
Powder for oral suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION: 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 acid. **PHARMACEUTICAL FORM:** 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. **CLINICAL PARTICULARS: Therapeutic Indications:** 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. **Posology and Method of Administration: Adults and children weighing 40 kg and over:** This suspension is not usually recommended for adults and children weighing 40 kg and over. **Children weighing less than 40 kg:** 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. 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 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. **Contraindications: 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. 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. Warnings and Precautions:** Please talk to your doctor, pharmacist, or nurse before giving Augmentin to your child if your child: has Pfeiffer's glandular fever or is being treated from liver or kidney problems, or has irregular water levels disorder. **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. **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 contains aspartame and maltodextrin:** Augmentin contains aspartame (E 951) as a source of phenylalanine and may be harmful to children born with a condition called phenylketonuria. 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. **Interactions:** 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 your child 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. **Possible side effects: Conditions you need to look out for: Allergic reaction:** 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, and collapse. **Contact a doctor immediately** if any of these symptoms occur to your child and 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. **Very common side effects:** Diarrhea (in adults). **Common side effects:** Fungal infection (*Candida* - yeast infection in the area of vagina, mouth, or skin folds), nausea, especially when taking high doses, vomiting, diarrhea (in children). Give Augmentin with a meal if this is applied. **Contact a doctor immediately if any of these side effects occur in your child.** 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*), and crystals in the urine. **PHARMACEUTICAL DATA: List of Excipients:** Aspartame (E 951), xanthan gum, silica, fumed silica, succinic acid, hypromellose, orange flavor 1* & 2*, raspberry flavor * and gold syrup flavor*. * It contains maltodextrin. **Special Precautions for Storage:** Store medicinal products out of reach of children. **Storage of 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. **Storage of 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. **Manufacturer:** Glaxo Wellcome Production*, 53100 Mayenne, France *member of GSK group of companies. **This package leaflet was revised last in December 2018.** Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com. To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com. All Quality complaints should be reported to the LOC Quality department mailbox Gulf-KSA.Product-Complaints@gsk.com. Prescribing information for Qatar. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: December 2018.