Prescribing Information for UAE
Augmentin 1 g 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

PHARMACEUTICAL FORM

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

CLINICAL PARTICULARS

Therapeutic Indications

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.

Medical Advice

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.

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.

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 for other medicines (including over-the-counter drugs) externally.

Interactions

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.

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.

Pregnancy, and breast-feeding

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.

Ability to perform tasks that require judgement, motor or cognitive skills

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

Adverse Reactions

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.

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.

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

PHARMACEUTICAL DATA

List of Excipients

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

Marketing Authorisation Holder:

GlaxoSmithKline Export Limited (Dubai Branch), 50199 Dubai, UAE.

Bulk Manufacturing & Primary Packaging by:

SmithKline Beecham Limited
Worthing, United Kingdom

Secondary Packaging & batch Releasing by:

Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.

This leaflet was last revised in June 2015.

Other precautions

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.

Reporting of side effects

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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: June 2015.

Abbreviated Prescribing Information for UAE
Augmentin 1 g tablets
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Augmentin contains amoxicillin trihydrate(875 mg) and clavulanic acid (125 mg). The ratio of Amoxicillin to Clavulanic acid is 7:1. **PHARMACEUTICAL FORM:** Augmentin 1 g (875/125) film-coated tablets: 14 film-coated tablets. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin should only be used when prescribed by a doctor for the exclusive treatment of 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, and 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 in adults with mild, moderate and severe infections is 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. **Medical Advice:** 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. **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. 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 for other medicines (including over-the-counter drugs) externally. **Interactions:** 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. 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. **Pregnancy, and breast-feeding:** 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. **Ability to perform tasks that require judgement, motor or cognitive skills:** This medicine may affect responsiveness and the ability to drive and use tools or machines. **Adverse Reactions:** 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 you have 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, and breathing problems in the form of asthma attacks and hay fever. 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. If you notice side effects not described here, you must inform your doctor or pharmacist. **PHARMACEUTICAL DATA: List of Excipients:** Colloidal silicon dioxide, sodium starch glycollate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicone 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. **Marketing Authorisation Holder:** GlaxoSmithKline Export Limited (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by** SmithKline Beecham Limited. Worthing, United Kingdom. **Secondary Packaging & batch Releasing by** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. **This leaflet was last revised in June 2015.** Trademarks are owned by or licensed to the GSK group of companies. **Other precautions:** 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. **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: June 2015.

Prescribing Information for UAE
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 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.

- 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.

Instructions for reconstitution

Remove cap and check foil-backed bottle seal is intact before using.

Shake bottle to loosen powder and remove the foil-backed seal. Add 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.

Strength	The volume of water to be added at reconstitution (ml)	The final volume of reconstituted oral suspension (ml)
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.

Medical Advice

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.

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 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, and breast-feeding

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

Ability to perform tasks that require judgment, motor or cognitive skills

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.

Adverse Reactions

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**.

Overdosage

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.

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.
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.

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.

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.

Manufacturer and Marketing Authorisation Holder

Marketing Authorisation Holder:

GlaxoSmithKline Export Limited (Dubai Branch), 50199 Dubai, UAE.

Bulk Manufacturing & Primary Packaging by Glaxo Wellcome
Production, 53100 MAYENNE, France

Secondary Packaging & batch Releasing by:

Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.

This leaflet was approved on 03/07/2018.

Reporting of side effects

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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 3 July 2018.

Abbreviated Prescribing Information for UAE
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 used in babies and children to treat middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections, and 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. 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. **Instructions for reconstitution:** Remove cap and check foil-backed bottle seal is intact before using. Shake bottle to loosen powder and remove the foil-backed seal. Add 92 ml of water to have a final volume of 100 ml reconstituted oral suspension, 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. 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. **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, 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, 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. **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. **Pregnancy, and breast-feeding:** If your child who is about to take this medicine is pregnant or breastfeeding, think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Ability to perform tasks that require judgment, motor, or cognitive skills:** 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. **Adverse Reactions:** Like all medicines, this medicine can cause side effects, although not everybody gets them. **Very common side effects:** diarrhea (in adults). **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. **Manufacturer and Marketing Authorisation Holder: Marketing Authorisation Holder:** GlaxoSmithKline Export Limited (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by** Glaxo Wellcome. Production, 53100 MAYENNE, France. **Secondary Packaging & batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. **This leaflet was approved on 03/07/2018.** **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 3 July 2018.

Prescribing Information for UAE
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 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 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.

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

Adults and children weighing 40 kg 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.

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.

Strength	The volume of water to be added at reconstitution (ml)	The final volume of reconstituted oral the suspension (ml)
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.

Medical Advice

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.

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.
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.

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.

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, and breast-feeding

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 operate machinery unless you are feeling well.

Overdosage

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.

Adverse Reactions

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 give 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 the 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.
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 about the safety of this medicine.

PHARMACEUTICAL DATA

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.

Manufacturer and Marketing Authorisation Holder
Marketing Authorisation Holder:
GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE.
Bulk Manufacturing & Primary Packaging by: Glaxo Wellcome
Production, 53100 MAYENNE, France
Secondary Packaging & batch Releasing by:
Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.
This leaflet was approved on 28/02/2018.

Reporting of side effects
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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Abbreviated Prescribing Information for UAE
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 used in babies and children to treat middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections, and bone and joint infections. **Posology and Method of Administration:** Always shake the bottle well before each dose, give with a meal, **s**pace 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. Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **Adults and children weighing 40 kg 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. The 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. **Instructions for reconstitution:** Check cap seal is intact before using. Shake bottle to loosen powder. Add 64 ml of water to get a 70 ml final volume of reconstituted oral suspension. 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. **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. **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, or are not passing water regularly. 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. **Pregnancy, and breast-feeding:** 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 operate machinery unless you are feeling well. **Overdosage:** 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. **Adverse Reactions:** Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine. **Common side effects:** These may affect up to 1 in 10 people, and include thrush (candida - a yeast infection of the vagina, mouth, or skin folds), feeling sick (nausea), especially when taking high doses - if affected give Augmentin with a meal, vomiting, or diarrhea (in children). **PHARMACEUTICAL DATA: 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. **Manufacturer and Marketing Authorisation Holder: Marketing Authorisation Holder:** GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by:** Glaxo Wellcome. Production, 53100 MAYENNE, France. **Secondary Packaging & batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. **This leaflet was approved on 28/02/2018.** Trademarks are owned by or licensed to the GSK group of companies. **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Prescribing Information for UAE
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 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

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.

Dosage and 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.

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 measuring spoon or cup. 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.

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	The volume of water to be added at reconstitution (ml)	The final volume of reconstituted oral suspension (ml)
250 mg/62.5 mg/5 ml	90	100

Shake the bottle well before each dose.

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 antibiotic 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.

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.

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.

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.

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 and breast-feeding and fertility

f 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.

Adverse Reactions

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.
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 the 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.
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.

PHARMACOLOGICAL PROPERTIES

PHARMACEUTICAL PARTICULARS

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 the 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 protect the environment.

Manufacturer and Marketing Authorisation Holder:

Marketing Authorisation Holder:

GlaxoSmithKline Export Limited (Dubai Branch), 50199 Dubai, UAE.
Bulk Manufacturing & Primary Packaging by: Glaxo Wellcome
Production, 53100 MAYENNE, France
Secondary Packaging & batch Releasing by:
Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.
This leaflet was approved on 27/04/2018.

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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 27 April 2018.

Abbreviated Prescribing Information for UAE
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 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: 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 and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections bone, and joint infections. **Dosage and Administration:** Always give this medicine as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **Adults and children weighing 40 kg 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:** You may be with a measuring spoon or cup. 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. **How to give Augmentin:** Always shake the bottle well before each dose. Give Augmentin 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:** 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 leukemia must not take Augmentin. **Warnings and Precautions: Do not give your child Augmentin** if 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. 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 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. **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. **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. **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 and breast-feeding and fertility: I**f 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. **Adverse Reactions 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:** diarrhoea (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 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 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 PARTICULARS: 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 the 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 protect the environment. **Marketing Authorisation Holder:** GlaxoSmithKline Export Limited Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by**: Glaxo Wellcome Production, 53100 MAYENNE, France. **Secondary Packaging & batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. **This leaflet was approved on 27/04/2018**. Trademarks are owned by or licensed to the GSK group of companies. 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 27 April 2018.

Prescribing Information for UAE
Augmentin 375 mg Tablets
Amoxicillin trihydrate and Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.

PHARMACEUTICAL FORM

Augmentin 375 mg film-coated tablets are white to off-white, oval-shaped tablets debossed with "Augmentin" on one side. They are packaged in blister packs inside a pouch, enclosed in a carton. The pouch contains a desiccant sachet. The desiccant must be kept inside the pouch and must not be eaten.

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 adults and children to treat the following infections:

- sinus infections
- urinary tract infections
- skin infections
- dental 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.

Adults and children weighing 40 kg and over

The usual dose is:

- 1 tablet three times a day
- Take with a meal.
- Swallow the tablets whole with a glass of water.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Augmentin oral suspension or sachets. Augmentin tablets are not recommended.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

Medical Advice

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.

Contraindications

Do not take Augmentin:

- if you are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine
- if you 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 you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Augmentin if you:

- 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 you, talk to your doctor or pharmacist before taking Augmentin.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you 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 you are taking Augmentin, to reduce the risk of any problems.

Blood and urine tests

If you are 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 you are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Interactions
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.
• If you are taking allopurinol (used for gout) with Augmentin, it may be more likely that you will have an allergic skin reaction.
• If you are taking probenecid (used for gout), your doctor may decide to adjust your 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 you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your 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.
Overdosage
If you take too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.
If you forget to take Augmentin
• If you forget to take a dose take it as soon as you remember.
• You should not take the next dose too soon, but wait around 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.
If you stop taking Augmentin
Keep taking Augmentin until the treatment is finished, even if you feel better. You need 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 or pharmacist.
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 you get 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 you get 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.
Uncommon side effects that may show up in your 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 your 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 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 you get 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 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

Side effects that may show up in your 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.

PHARMACEUTICAL DATA

List of Excipients

Tablet core – magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose. Film coat – titanium dioxide (E171), hypromellose, macrogol (4000, 6000), and silicone oil (dimeticone).

Storage

• Keep this medicine out of the sight and reach of children.
• 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.
• 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.
• Do not use if the tablets are chipped or damaged.
• 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.

Marketing Authorisation Holder:

GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE.

Bulk Manufacturing & Primary Packaging by:

SmithKline Beecham Limited*, Worthing UK.

Secondary Packaging & Batch Releasing by:

Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.
*Member of the GlaxoSmithKline group of companies

This leaflet was last revised in January 2019.

Reporting of side effects

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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: January 2019.

Abbreviated Prescribing Information for UAE
Augmentin 375 mg Tablets
Amoxicillin trihydrate and Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 375 mg film-coated tablets are white to off-white, oval-shaped tablets debossed with "Augmentin" on one side. They are packaged in blister packs inside a pouch, enclosed in a carton. The pouch contains a desiccant sachet. The desiccant must be kept inside the pouch and must not be eaten. **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 adults and children to treat sinus infections, urinary tract infections, skin infections, and dental 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. **Adults and children weighing 40 kg and over:** The usual dose is 1 tablet three times a day. Take with a meal, swallow the tablets whole with a glass of water, space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour, and do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor. **Children weighing less than 40 kg:** Children aged 6 years or less should preferably be treated with Augmentin oral suspension or sachets. Augmentin tablets are not recommended. **Patients with kidney and liver problems:** If you have kidney problems the dose might be changed. A different strength or different medicine may be chosen by your doctor. If you have liver problems you may have more frequent blood tests to check how your liver is working. **Contraindications:** Do not take Augmentin**,** if you are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine, or if you 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 you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. **Warnings and Precautions:** Talk to your doctor or pharmacist before taking Augmentin if you have glandular fever, are being treated for liver or kidney problems, or are not passing water regularly. **Interactions:** Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. **Pregnancy, breast-feeding, and fertility:** If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your 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. **Overdosage:** If you take too much Augmentin, take the medicine carton or bottle to show the doctor. **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. **Common side effects:** These may affect up to 1 in 10 people; thrush (candida - a yeast infection of the vagina, mouth or skin folds), and feeling sick (nausea), especially when taking high doses. If affected take Augmentin with a meal. **PHARMACEUTICAL DATA: List of Excipients:** Tablet core – magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose. Film coat – titanium dioxide (E171), hypromellose, macrogol (4000, 6000), and silicone oil (dimeticone). **Storage:** Keep this medicine out of the sight and reach of children. 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. 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. Do not use if the tablets are chipped or damaged. 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. **Marketing Authorisation Holder:** GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by:** SmithKline Beecham Limited*, Worthing UK. **Secondary Packaging & Batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. *Member of the GlaxoSmithKline group of companies **This leaflet was last revised in January 2019.** **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: January 2019.

Prescribing Information for UAE
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). Below is the detailed composition of the various commercially available dosage forms for children (where applicable, after preparation):

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

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);
- Infections of the kidneys, bladder and urinary tract;
- Infections of the reproductive system (gonorrhoea, secretion of mucus);
- Gynaecological infections;
- Infections of the skin and soft tissues (furuncles, abscesses, etc.).

Dosage and 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.

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 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**.**

Preparation of the suspensions

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

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.

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 (amniorrhexis) 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.

Adverse Reactions

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, hyperkinesis (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.

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

PHARMACOLOGICAL PROPERTIES

PHARMACEUTICAL PARTICULARS

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.

Marketing Authorisation Holder:

GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE

Bulk Manufacturing & Primary Packaging by: Glaxo Wellcome Production, 53100 MAYENNE, France

Secondary Packaging & batch Releasing by:

Neopharma, ICAD, Mussafah, Abu Dhabi, UAE
This leaflet was last revised in January 2018.

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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: January 2018.

Abbreviated Prescribing Information for UAE
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). The detailed composition of the commercially available dosage form for children: Augmentin 457 mg/5 mL (400/57) , 5 mL suspension contains Amoxicillin 400 mg , Clavulanic acid 57 mg , Ratio of amoxicillin to clavulanic acid is 7 : 1 **PHARMACEUTICAL FORM:** Clear, glass bottles, containing an off-white dry powder. **CLINICAL PARTICULARS:** 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); infections of the kidneys, bladder and urinary tract; infections of the reproductive system (gonorrhoea, secretion of mucus); gynaecological infections; infections of the skin and soft tissues (furuncles, abscesses, etc.). **Dosage and Administration:** Posology/Use: Augmentin should preferably be taken at the start of meals. In this way, optimum efficacy and tolerance are achieved. Children: 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, 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 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. 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 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 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:** 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 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. **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. Breast-feeding: Augmentin should not be used during breast-feeding or breast-feeding should be discontinued. **Adverse Reactions:** 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. 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 bellyache 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. For patients with phenylketonuria: the suspensions are sweetened with aspartame. **PHARMACEUTICAL PARTICULARS**: 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 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 the detailed summary of product characteristics. **Marketing Authorisation Holder**: GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by**: Glaxo Wellcome Production, 53100 MAYENNE, France. **Secondary Packaging & batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. This leaflet was last revised in January 2018. 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: January 2018.

Prescribing Information for UAE
Augmentin 625 mg Tablets
Amoxicillin trihydrate and Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.

PHARMACEUTICAL FORM

Augmentin 625 mg film-coated tablets are white to off-white, oval-shaped tablets debossed with "AC" and a scoreline on one side.

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 adults 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 take this medicine exactly as your doctor or pharmacist has told you.

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

Adults and children weighing 40 kg and over

The usual dose is:

- 1 tablet three times a day
- Take with a meal.
- Swallow the tablets whole with a glass of water.
- Tablets can be broken along the scoreline to make them easier to swallow.

You must take both pieces of the tablet at the same time.

- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Augmentin oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Augmentin tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

Medical Advice

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.

Contraindications

Do not take Augmentin:

- if you are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine
- if you 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 you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Augmentin if you:

- 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 you, talk to your doctor or pharmacist before taking Augmentin.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you 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 you are taking Augmentin, to reduce the risk of any problems.

Blood and urine tests

If you are 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 you are taking Augmentin. This is because Augmentin can affect the results of these types of tests.

Interactions

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

• If you are taking allopurinol (used for gout) with Augmentin, it may be more likely that you will have an allergic skin reaction.
• If you are taking probenecid (used for gout), your doctor may decide to adjust your 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 you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your 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.

Overdosage

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

If you forget to take Augmentin

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

If you stop taking Augmentin

Keep taking Augmentin until the treatment is finished, even if you feel better. You need 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 or pharmacist.

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 you get 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 you get 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.
Uncommon side effects that may show up in your 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 your 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 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 you get 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 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.
Side effects that may show up in your 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.
PHARMACEUTICAL DATA
List of Excipients
Tablet core - magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose. Film-coat - titanium dioxide (E171), hypromellose, macrogol (4000, 6000) and silicone oil (dimeticone).
Storage
• Keep this medicine out of the sight and reach of children.
• 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.
• 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.
• Do not use if the tablets are chipped or damaged.
• 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
Marketing Authorisation Holder:
GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE.
Bulk Manufacturing & Primary Packaging by:
SmithKline Beecham Limited*, Worthing UK.
Secondary Packaging & Batch Releasing by:
Neopharma, ICAD, Mussafah, Abu Dhabi, UAE.
*Member of the GlaxoSmithKline group of companies
This leaflet was last revised on 28 February 2018.

Reporting of side effects
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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Abbreviated Prescribing Information for UAE
Augmentin 625 mg Tablets
Amoxicillin trihydrate and Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 625 mg film-coated tablets are white to off-white, oval-shaped tablets debossed with "AC" and a scoreline on one side. **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 adults and children to treat middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections, and 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. **Adults and children weighing 40 kg and over:** The usual dose is 1 tablet three times a day. Take with a meal. Swallow the tablets whole with a glass of water. Tablets can be broken along the scoreline to make them easier to swallow. You must take both pieces of the tablet at the same time. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not take Augmentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor. **Children weighing less than 40 kg:** Children aged 6 years or less should preferably be treated with Augmentin oral suspension or sachets. Ask your doctor or pharmacist for advice when giving Augmentin tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg. **Patients with kidney and liver problems:** If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor. If you have liver problems you may have more frequent blood tests to check how your liver is working. **Contraindications:** Do not take Augmentin if you are allergic to amoxicillin, clavulanic acid, penicillin, or any of the other ingredients of this medicine if you 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 you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic. **Interactions:** Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. **Pregnancy, breast-feeding, and fertility:** If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your 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. **Overdosage:** If you have too much Augmentin, talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor. **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. **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, or diarrhea (in children). **PHARMACEUTICAL DATA: List of Excipients:** Tablet core - magnesium stearate, sodium starch glycolate type A, colloidal anhydrous silica, microcrystalline cellulose. Film-coat - titanium dioxide (E171), hypromellose, macrogol (4000, 6000) and silicone oil (dimeticone). **Storage:** Keep this medicine out of the sight and reach of children. 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. 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. Do not use if the tablets are chipped or damaged. 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. **Marketing Authorisation Holder:** GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary Packaging by:** SmithKline Beecham Limited*, Worthing UK. **Secondary Packaging & Batch Releasing by:** Neopharma, ICAD, Mussafah, Abu Dhabi, UAE. *Member of the GlaxoSmithKline group of companies. **This leaflet was last revised on 28 February 2018.** **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Prescribing Information for UAE
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 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 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**.**

Concentration	The volume of water to be added at reconstitution (ml)	The final volume of reconstituted oral suspension (ml)
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.

Medical Advice

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.

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

Take special care with Augmentin

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, and breast-feeding

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.

Adverse Reactions

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.

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.

Contents of the pack

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 liquid mixture called a suspension.

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.

Marketing Authorisation Holder:

AUGMENTIN ES and AUGMENTIN are trademarks of the GlaxoSmithKline group of companies

This leaflet was last revised in 03/2015

GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE.

Bulk Manufacturing & Primary Packaging by:

GlaxoWellcome Production*, Mayenne, France

Secondary Packaging & batch Releasing by:

Neopharma, ACAD, Mussafah, Abu Dhabi, UAE.
*Member of the GlaxoSmithKline group of companies.

Reporting of side effects

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

Abbreviated Prescribing Information for UAE
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 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 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. **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 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). **Warnings and Precautions: 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. **Take special care with Augmentin:** 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. 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:** 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, and breast-feeding:** If your child who is about to take Augmentin is pregnant or breast-feeding, please tell your doctor or pharmacist. **Adverse Reactions: 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** 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 If this occurs, take Augmentin before food vomiting diarrhea (in children). **PHARMACEUTICAL DATA: List of Excipients:** Aspartame (E951), xanthan gum, colloidal hydrated silicon, colloidal anhydrous silica, artificial strawberry cream flavor, and water. **Contents of the pack:** 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 suspension. **Marketing Authorisation Holder:** AUGMENTIN ES and AUGMENTIN are trademarks of the GlaxoSmithKline group of companies. **This leaflet was last revised in 03/2015.** GlaxoSmithKline Export Limited* (Dubai Branch), 50199 Dubai, UAE. **Bulk Manufacturing & Primary by: GlaxoWellcome Production*, Mayenne, France Secondary Packaging & batch Releasing by:** Neopharma, ACAD, Mussafah, Abu Dhabi, UAE. *Member of the group of companies. **Other precautions** 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. **Reporting of side effects:** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: March 2015.

Prescribing Information for UAE
Augmentin™ Infant Drops
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

AUGMENTIN infant drops contain 50 mg amoxicillin (as amoxicillin trihydrate) and 12.5 mg clavulanic acid (as potassium clavulanate) per 1 ml.

PHARMACEUTICAL FORM

Dry powder for reconstitution in water, at time of dispensing, to form an oral sugar-free suspension.

CLINICAL PARTICULARS

Indications

AUGMENTIN should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.

AUGMENTIN infant drops 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, lobar and bronchopneumonia.

Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.

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

Bone and joint infections e.g. osteomyelitis.

Other infections e.g. intra-abdominal sepsis.

Susceptibility to *AUGMENTIN* will vary with geography and time (see Pharmacological Properties, Pharmacodynamics for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Infections caused by amoxicillin-susceptible organisms are amenable to *AUGMENTIN* treatment due to its amoxicillin content. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with *AUGMENTIN*-susceptible β-lactamase producing organisms may therefore be treated with *AUGMENTIN*.

Dosage and Administration

The dosage depends on the age, weight and renal function of the patient and the severity of the infection.

Dosages are expressed throughout in terms of amoxicillin-/clavulanate content except when doses are stated in terms of an individual component.

To minimise potential gastrointestinal intolerance, administer at the start of a meal.

The absorption of amoxicillin-clavulanate is optimised when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

Therapy can be started parenterally and continued with an oral preparation.

• Children

Dosage should be expressed in terms of the age of the child and either in mg/kg/day (given in 2 or 3 divided doses) or ml of suspension per dose or equivalent for other presentations.

Children weighing 40 kg and over should be dosed according to the adult recommendations.

Children up to 12 years

	Three times daily (4:1) formulations
Lower dose (mg/kg/day)	20/5 to 40/10
Higher dose (mg/kg/day)	40/10 to 60/15

The lower dose is recommended for infections such as skin and soft tissue and recurrent tonsillitis.

The higher dose is recommended for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections.

No clinical data are available on doses of these formulations higher than 40/10 mg/kg/day in children under 2 years.

The 8:1 ratio formulation is recommended for dosing at 40/5 to 80/10 mg/kg/day (in three divided doses) in children aged 1 to 30 months, depending upon the severity of the infection.

Premature

No dosage recommendation can be made for this category.

• Renal impairment

Dosage adjustments are based on the maximum recommended level of amoxicillin.

Creatinine clearance greater than 30 ml/min:	No adjustment is necessary.
Creatinine clearance 10 to 30 ml/min:	15/3.75 mg/kg given twice daily (maximum 500/125 mg twice daily).
Creatinine clearance less than 10 ml/min:	15/3.75 mg/kg given as a single daily dose (maximum 500/125 mg).

In the majority of cases, parenteral therapy, where available, may be preferred.

Haemodialysis

15/3.75 mg/kg/day given as a single daily dose.

Prior to haemodialysis, one additional dose of 15/3.75 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15/3.75 mg/kg should be administered after haemodialysis.

• Hepatic impairment

Dose with caution; monitor hepatic function at regular intervals.

There are insufficient data on which to base a dosage recommendation.

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 *AUGMENTIN*-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.
Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.
Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving *AUGMENTIN* and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.
AUGMENTIN should be used with caution in patients with evidence of hepatic dysfunction.
In patients with renal impairment, *AUGMENTIN* dosage should be adjusted as recommended in the Dosage and Administration section.
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 2.5 mg aspartame per 1 ml, 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.
In the literature, there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If coadministration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of *AUGMENTIN.*
In patients receiving mycophenolate mofetil, reduction in the pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in the pre-dose level may not accurately represent changes in overall MPA exposure.

Pregnancy and Lactation

Reproduction studies in animals (mice and rats) with orally and parenterally administered *AUGMENTIN* have shown no teratogenic effects. In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with *AUGMENTIN* may be associated with an increased risk of necrotizing 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. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no detrimental effects for the infant.

Effects on Ability to Drive and Use Machines

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

Adverse Reactions

Data from large clinical trials were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.
The following convention has been used for the classification of frequency:
very common >1/10
common >1/100 and <1/10
uncommon >1/1000 and <1/100
rare >1/10,000 and <1/1000
very rare <1/10,000.

Infections and infestations

Common: Mucocutaneous candidiasis

Blood and lymphatic system disorders

Rare: Reversible leucopenia (including neutropenia) and thrombocytopenia
Very rare: Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time

Immune system disorders

Very rare: Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis

Nervous system disorders

Uncommon: Dizziness, headache
Very rare: Reversible hyperactivity and convulsions. Convulsions may occur in patients with impaired renal function or those receiving high doses.

Gastrointestinal disorders

Common: Diarrhoea, nausea, vomiting
Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking *AUGMENTIN* at the start of a meal.
Uncommon: Indigestion
Very rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis).
Black hairy tongue
Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

Hepatobiliary disorders

Uncommon: A moderate rise in AST and/or ALT has been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown
Very rare: Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.
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.

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. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Skin and subcutaneous tissue disorders

Uncommon: Skin rash, pruritus, urticaria

Rare: Erythema multiforme

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

If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.

Renal and urinary disorders

Very rare Interstitial nephritis, crystalluria

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 may be removed from the circulation by haemodialysis.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in *AUGMENTIN* infant drops anticipates this defence mechanism by blocking the β-lactamase enzymes, thus rendering the organisms susceptible to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.

Clavulanate by itself has little antibacterial activity; however, in association with amoxicillin as *AUGMENTIN,* it produces an antibiotic agent of broad-spectrum with wide application in hospital and general practice.

In the list below, organisms are categorised according to their in vitro susceptibility to *AUGMENTIN.*

In vitro susceptibility of micro-organisms to *AUGMENTIN*
Where clinical efficacy of *AUGMENTIN* has been demonstrated in clinical trials this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxicillin, it can be considered susceptible to *AUGMENTIN*.
Commonly susceptible species
Gram-positive aerobes: *Bacillus anthracis* *Enterococcus faecalis* *Listeria monocytogenes* *Nocardia asteroides* *Streptococcus pyogenes*†* *Streptococcus agalactiae*†* *Streptococcus spp. (other β-hemolytic) *†* *Staphylococcus aureus (methicillin-susceptible)** *Staphylococcus saprophyticus (methicillin-susceptible)* *Coagulase-negative staphylococcus (methicillin-susceptible)*
Gram-negative aerobes: *Bordetella pertussis* *Haemophilus influenza** *Haemophilus parainfluenzae* *Helicobacter pylori* *Moraxella catarrhalis** *Neisseria gonorrhoeae* *Pasteurella multocida* *Vibrio cholerae*
Other: *Borrelia burgdorferi* *Leptospira ictterohaemorrhagiae* *Treponema pallidum*
Gram-positive anaerobes: *Clostridium spp.* *Peptococcus niger* *Peptostreptococcus magnus* *Peptostreptococcus micros* *Peptostreptococcus spp.*
Gram-negative anaerobes: *Bacteroides fragilis* *Bacteroides spp.* *Capnocytophaga spp.* *Eikenella corrodens* *Fusobacterium nucleatum* *Fusobacterium spp.* *Porphyromonas spp.* *Prevotella spp.*
Species for which acquired resistance may be a problem
Gram-negative aerobes:

*Escherichia coli**
Klebsiella oxytoca
*Klebsiella pneumoniae**
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Proteus spp.
Salmonella spp.
Shigella spp.
Gram-positive aerobes:
Corynebacterium spp.
Enterococcus faecium
Streptococcus pneumoniae†*
Viridans group streptococcus
Inherently resistant organisms
Gram-negative aerobes:
Acinetobacter spp.
Citrobacter freundii
Enterobacter spp.
Hafnia alvei
Legionella pneumophila
Morganella morganii
Providencia spp.
Pseudomonas spp.
Serratia spp.
Stenotrophomas maltophilia
Yersinia enterolitica
Others:
Chlamydia pneumoniae
Chlamydia psittaci
Chlamydia spp.
Coxiella burnetti
Mycoplasma spp.

Pharmacokinetics

The pharmacokinetics of the two components of *AUGMENTIN* are closely matched. Peak serum levels of both occur about 1 hour after oral administration. Absorption of *AUGMENTIN* is optimised at the start of a meal.

Doubling the dosage of *AUGMENTIN* approximately doubles the serum levels achieved.

Both clavulanate and amoxicillin have low levels of serum binding; about 70% remains free in the serum.

Pre-clinical Safety Data

No further information of relevance.

PHARMACEUTICAL PARTICULARS

List of Excipients

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

Incompatibilities

None known.

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

The dry powder should be stored in unopened containers in a dry place at below 25°C.

Reconstituted suspensions should be stored in a refrigerator (2-8°C) and used within seven days.

Nature and Contents of Container

Glass bottles with screw caps, containing an off-white dry powder. A syringe dosing device is also included.

Instructions for Use/Handling

• Check cap seal is intact before use.
• Invert and shake the bottle to loosen powder.
• Fill the bottle with water to just below the mark on the bottle label.

Invert and shake well, then top up with water to the mark. Invert and shake again.

• Allow to stand for 5 minutes to ensure full dispersion.
• Shake well before taking each dose.

If a syringe is provided:

Once reconstituted, the adaptor that is supplied with the syringe dosing device should be inserted into the neck of the bottle before replacing the screw cap.

Not all presentations are available in every country.

Manufactured by:

SmithKline Beecham Limited*
Worthing, UK
*Member of the GlaxoSmithKline group of companies

AUGMENTIN is a trademark of the GlaxoSmithKline group of companies

Version number: 21
Date of issue: 18 January 2013
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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Abbreviated Prescribing Information for UAE
Augmentin Infant Drops
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: *AUGMENTIN* infant drops contain 50 mg amoxicillin (as amoxicillin trihydrate) and 12.5 mg clavulanic acid (as potassium clavulanate) per 1 ml. **PHARMACEUTICAL FORM:** Dry powder for reconstitution in water, at time of dispensing, to form an oral sugar-free suspension. **CLINICAL PARTICULARS: Indications:** *AUGMENTIN* should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. *AUGMENTIN* infant drops 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, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Bone and joint e.g. osteomyelitis. Other infections e.g. intra-abdominal sepsis. Susceptibility to *AUGMENTIN* will vary with geography and time. Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Infections caused by amoxicillin-susceptible organisms are amenable to *AUGMENTIN* treatment due to its amoxicillin content. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with *AUGMENTIN*-susceptible β-lactamase producing organisms may therefore be treated with *AUGMENTIN*. **Dosage and Administration:** To minimise potential gastrointestinal intolerance, administer at the start of a meal. The absorption of amoxicillin-clavulanate is optimised when taken at the start of a meal. Treatment should not be extended beyond 14 days without review. Therapy can be started parenterally and continued with an oral preparation. **Children:** Dosage should be expressed in terms of the age of the child and either in mg/kg/day (given in 2 or 3 divided doses) or ml of suspension per dose or equivalent for other presentations. Children weighing 40 kg and over should be dosed according to the adult recommendations. Children up to 12 years: The Lower dose is 20/5 to 40/10 mg/kg/day, three times daily (4:1) formulations**.** a Higher dose 40/10 to 60/15 mg/kg/day. The lower dose is recommended for infections such as skin and soft tissue and recurrent tonsillitis. The higher dose is recommended for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections. The 8:1 ratio formulation is for dosing at 40/5 to 80/10 mg/kg/day (in three divided doses) in children aged 1 to 30 months, depending upon the severity of the infection. **Renal impairment:** Dosage adjustments are based on the maximum recommended level of amoxicillin. In the majority of cases, parenteral therapy, where available, may be preferred. **Haemodialysis:** 15/3.75 mg/kg/day given as a single daily dose. Prior to haemodialysis, one additional dose of 15/3.75 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15/3.75 mg/kg should be administered after haemodialysis. **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 *AUGMENTIN*-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. Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further. Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving *AUGMENTIN* and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation. *AUGMENTIN* should be used with caution in patients with evidence of hepatic dysfunction. In patients with renal impairment, *AUGMENTIN* dosage should be adjusted as recommended in the Dosage and Administration section. 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 2.5 mg aspartame per 1 ml, 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. In the literature, there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If coadministration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of *AUGMENTIN.* In patients receiving mycophenolate mofetil, reduction in the pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in the pre-dose level may not accurately represent changes in overall MPA exposure. **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. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no detrimental effects for the infant. **Adverse Reactions**: Common: Mucocutaneous candidiasis, diarrhoea, nausea, vomiting, If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued. **Overdose:** Gastrointestinal symptoms may be treated symptomatically with attention to the water-electrolyte balance. *AUGMENTIN* may be removed from the circulation by haemodialysis. **PHARMACEUTICAL PARTICULARS: List of Excipients:** Xanthum gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange and golden syrup dry flavours. **Shelf Life:** The expiry date is indicated on the packaging. **Special Precautions: for Storage:** The dry powder should be stored in unopened containers in a dry place at below 25°C. Reconstituted suspensions should be stored in a refrigerator (2-8°C) and used within seven days. **Nature and Contents of Container:** Glass bottles with screw caps, containing an off-white dry powder. A syringe dosing device is also included. **Instructions for Use/Handling:** Check cap seal is intact before use. Invert and shake the bottle to loosen powder. Fill the bottle with water to just below the mark on the bottle label. Invert and shake well, then top up with water to the mark. Invert and shake again. Allow to stand for 5 minutes to full dispersion. Shake well before taking each dose. If a syringe is provided: Once reconstituted, the adaptor that is supplied with the syringe dosing device should be inserted into the neck of the bottle before replacing the screw cap. Not all presentations are available in every country. **Manufactured by**: SmithKline Beecham *Worthing, UK *Member of the GlaxoSmithKline group of companies AUGMENTIN is a trademark of the GlaxoSmithKline group of companies **Version number: 21 Date of issue: 18 January 2013.** 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 UAE. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.