Prescribing Information for Bahrain
Augmentin™ 1 g
Amoxicillin trihydrate + Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Augmentin 1 g tablet contains 875 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

PHARMACEUTICAL FORM

White to off-white, film-coated tablets debossed with "AC" on both sides and a scoreline on one side. The scoreline is only to facilitate breaking and ease of swallowing and not to divide into equal doses.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community-acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and Method of Administration

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Augmentin that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below

The use of alternative presentations of Augmentin (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.

For adults and children ≥ 40 kg, this formulation of Augmentin provides a total daily dose of 1750 mg amoxicillin/ 250 mg clavulanic acid with twice-daily dosing and 2625 mg amoxicillin/375 mg clavulanic acid with three times daily dosing when administered as recommended below.

For children < 40 kg, this formulation of Augmentin provides a maximum daily dose of 1000-2800 mg amoxicillin/143-400 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid.

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.

Adults and children ≥ 40 kg

Recommended doses:

- standard dose: (for all indications) 875 mg/125 mg two times a day;
- higher dose - (particularly for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections): 875 mg/125 mg three times a day.

Children < 40 kg

Children may be treated with Augmentin tablets, suspensions or paediatric sachets.

Recommended doses:

- 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses;
- up to 70 mg/10 mg/kg/day given as two divided doses may be considered for some infections (such as otitis media, sinusitis and lower respiratory tract infections).

As the tablets cannot be divided, children weighing less than 25 kg must not be treated with Augmentin tablets.

The table below presents the received dose (mg/kg body weight) in children weighing 25 kg to 40 kg upon administering a single 875/125 mg tablet.

Body weight [kg]	40	35	30	25	Single dose recommended [mg/kg body weight] (see above)
Amoxicillin [mg/kg body weight] per single dose (1 film-coated tablet)	21.9	25.0	29.2	35.0	12.5 – 22.5 (up to 35)
Clavulanic acid [mg/kg body weight] per single dose (1 film-coated tablet)	3.1	3.6	4.2	5.0	1.8 – 3.2 (up to 5)

Children weighing less than 25 kg should preferably be treated with Augmentin suspension or paediatric sachets. No clinical data are available for Augmentin 7:1 formulations regarding doses higher than 45 mg/6.4 mg per kg per day in children under 2 years There are no clinical data for Augmentin 7:1 formulations for patients under 2 months of age. Dosing recommendations in this population therefore cannot be made.

Elderly

No dose adjustment is considered necessary.

Renal impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

In patients with creatinine clearance less than 30 ml/min, the use of Augmentin presentations with amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose, adjustments are available.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

Method of administration

Augmentin is for oral use.

Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid. Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation.

Contraindications

Amoxicillin-clavulanate is contra-indicated:

- in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins
- in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction.

Warnings and Precautions

Before initiating therapy with amoxicillin-clavulanate, 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. If an allergic reaction occurs, amoxicillin-clavulanate therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, i.v. steroids and airway management, including intubation, may also be required.

Amoxicillin-clavulanate 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.

In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin-clavulanate 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.

Amoxicillin-clavulanate should be used with caution in patients with evidence of hepatic dysfunction.

In patients with renal impairment, the dosage should be adjusted according to the degree of impairment.

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.

Amoxicillin-clavulanate Suspensions/Sachets/Chewable Tablets (where applicable), contain aspartame, which is a source of phenylalanine and so 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 amoxicillin-clavulanate may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.

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 amoxicillin-clavulanate and allopurinol.

In common with other antibiotics, amoxicillin-clavulanate 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 amoxicillin.

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

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin-clavulanate 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 amoxicillin-clavulanate may be associated with an increased risk of necrotizing enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant.

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

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
Adults:
Very common: Diarrhoea
Common: Nausea, vomiting
Children:
Common: Diarrhoea, nausea, vomiting
All populations:
Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin-clavulanate 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+.
+This statement is core safety for the syrup, suspension and chewable tablet formulations.
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.
Children (additional statement):
These events have been very rarely reported in children.
All populations:
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 generalized exanthemous pustulosis (AGEP)
If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.
Renal and urinary disorders
Very rare: Interstitial nephritis, crystalluria.
Overdosage
Symptoms and Signs
Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.
Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.
Treatment
GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance.
Amoxicillin-clavulanate can be removed from the circulation by haemodialysis.
Children (additional statement):
A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.
Drug abuse and dependence
Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound.
PHARMACEUTICAL DATA
List of Excipients
Colloidal silicon dioxide, sodium starch glycollate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicon oil).
Incompatibilities
None known.
Shelf-life
As indicated on the outer packaging.
Special Precautions for Storage
Store in a dry place at or below 30°C.
Store in the original package in order to protect from moisture.
Tablets in desiccated pouch packs should be used within 14 days of opening.
Nature and Contents of Container
Only moisture-proof containers should be used. Augmentin™ 1 g is supplied in a carton containing 14 tablets in blisters inside a desiccated pouch.
Manufactured by:
SmithKline Beecham Limited*
Worthing, United Kingdom
*Member of the GlaxoSmithKline group of companies

GDS Version Number: 21

Version Date: 18 January 2013

Reporting of adverse events

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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013

Abbreviated Prescribing Information for Bahrain
Augmentin™ 1 g
Amoxicillin trihydrate + potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Each Augmentin 1 g tablet contains 875 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate). **PHARMACEUTICAL FORM:** White to off-white, film-coated tablets debossed with "AC" on both sides and a scoreline on one side. The scoreline is only to facilitate breaking and ease of swallowing and not to divide into equal doses. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is indicated in adults and children for the treatment of acute bacterial sinusitis (adequately diagnosed), acute otitis media, acute exacerbations of chronic bronchitis (adequately diagnosed), community-acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, bone and joint infections, in particular osteomyelitis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **Posology and Method of Administration:** Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component. The dose of Augmentin that is selected to treat an individual infection should take into account the expected pathogens and their likely susceptibility to antibacterial agents, the severity and the site of the infection, the age, weight and renal function of the patient. The use of alternative presentations of Augmentin (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary. For adults and children ≥ 40 kg, this formulation of Augmentin provides a total daily dose of 1750 mg amoxicillin/ 250 mg clavulanic acid with twice-daily dosing and 2625 mg amoxicillin/375 mg clavulanic acid with three times daily dosing when administered. For children < 40 kg, this formulation of Augmentin provides a maximum daily dose of 1000-2800 mg amoxicillin/143-400 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid. The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review. For adults and children ≥ 40 kg**,** the recommended doses are standard dose: (for all indications) 875 mg/125 mg two times a day; or a higher dose - (particularly for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections): 875 mg/125 mg three times a day. For children < 40 kg**:** Children may be treated with Augmentin tablets, suspensions or paediatric sachets. The recommended doses are 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses; or up to 70 mg/10 mg/kg/day given as two divided doses may be considered for some infections (such as otitis media, sinusitis and lower respiratory tract infections). As the tablets cannot be divided, children weighing less than 25 kg must not be treated with Augmentin tablets. Children weighing less than 25 kg should preferably be treated with Augmentin suspension or paediatric sachets. No clinical data are available for Augmentin 7:1 formulations regarding doses higher than 45 mg/6.4 mg per kg per day in children under 2 years There are no clinical data for Augmentin 7:1 formulations for patients under 2 months of age. Dosing recommendations in this population therefore cannot be made. Elderly: No dose adjustment is considered necessary.Renal impairment: No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min. In patients with creatinine clearance less than 30 ml/min, the use of Augmentin presentations with amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose adjustments are available. Hepatic impairment: Dose with caution and monitor hepatic function at regular intervals. Method of administration: Augmentin is for oral use. Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid. Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation. **Contraindications:** Amoxicillin-clavulanate is contraindicated in patients with a history of hypersensitivity to beta-lactams and patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction. **Warnings and Precautions:** Before initiating therapy with amoxicillin-clavulanate, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, or other allergens. Serious and occasionally fatal hypersensitivity reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, amoxicillin-clavulanate therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, i.v. steroids and airway management, including intubation, may also be required. Amoxicillin-clavulanate should be avoided if infectious mononucleosis is suspected. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy. Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin-clavulanate 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. Amoxicillin-clavulanate should be used with caution in patients with evidence of hepatic dysfunction. In patients with renal impairment, the dosage should be adjusted according to the degree of impairment. 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. Amoxicillin-clavulanate Suspensions/Sachets/Chewable Tablets (where applicable), contain aspartame, which is a source of phenylalanine and so should be used with caution in patients with phenylketonuria. **Interactions:** Concomitant use of probenecid is not recommended. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. In common with other antibiotics, amoxicillin-clavulanate may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. 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. **Pregnancy and Lactation: Pregnancy:** As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician. **Lactation:** Amoxicillin-clavulanate 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. **Ability to perform tasks that require judgement, motor or cognitive skills:** Adverse effects on the ability to drive or operate machinery have not been observed. **Adverse Reactions:** The commonly (>1/100 and <1/10) observed side effects are common: Mucocutaneous candidiasis, nausea, and vomiting. **Treatment of overdosage: Symptoms and Signs:** GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin-clavulanate can be removed from the circulation by haemodialysis. **PHARMACEUTICAL DATA: List of Excipients:** Colloidal silicon dioxide, sodium starch glycollate, magnesium stearate (E572), microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol, dimethicone (silicon oil). **Shelf-life:** As indicated on the outer packaging. **Special Precautions for Storage:** Store in a dry place at or below 30°C. Store in the original package in order to protect from moisture. Tablets in desiccated pouch packs should be used within 14 days of opening. **Nature and Contents of Container:** Only moisture-proof containers should be used. Augmentin™ 1 g is supplied in a carton containing 14 tablets in blisters inside a desiccated pouch. **Manufactured by:** SmithKline Beecham Limited*, Worthing, United Kingdom, *Member of the GlaxoSmithKline group of companies. AUGMENTIN is a trademark of the GlaxoSmithKline group of companies. **GDS Version Number: 21, Version Date: 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Prescribing Information for Bahrain
Augmentin 156 mg/5 ml suspension
Co-amoxiclav (Amoxicillin trihydrate + Potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

156 mg/5 ml Suspension co-amoxiclav (Amoxicillin trihydrate +Potassium clavulanate). 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.

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.

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.

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 the volume of water (as indicated below), close, invert, and shake well. Alternatively, shake the bottle to loosen the powder then fill the bottle with water to just below the line on the label. Close, invert and shake well, then top up with water exactly to the line. Close, invert, and again shake well.

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.

Advice/medical education

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

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

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.

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.
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, breast-feeding and fertility

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

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Possible side effects

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

Conditions you need to look out for

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

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

Inflammation of 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.

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.

PHARMACEUTICAL DATA

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

Special Precautions for Storage
Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, store in a refrigerator and use within 7 days. Do not freeze. Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help you to protect the environment.

Manufactured by:
Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France.

This leaflet was approved on 03/07/2018.

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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 03 July 2018.

Abbreviated Prescribing Information for Bahrain
Augmentin 156 mg/5 ml suspension
Co-amoxiclav (Amoxicillin trihydrate + potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION: 156 mg/5 ml Suspension co-amoxiclav (Amoxicillin trihydrate +Potassium clavulanate). 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. 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. 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. **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 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. **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, they are being treated for liver or kidney problems, or they 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. 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. **Pregnancy, breast-feeding and fertility:** If your child who is about to take this medicine is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Driving and using machines:** Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. **Common side effects:** Affect up to 1 in 10 people as thrush (*candida* - a yeast infection of the vagina, mouth or skin folds), feeling sick (nausea), or especially when taking high doses. If affected take Augmentin with a meal. **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. **PHARMACEUTICAL DATA: List of Excipients:** Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange, and golden syrup dry flavors. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, store in a refrigerator and use within 7 days. Do not freeze. Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help you to protect the environment. **Manufactured by:** Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France. **This leaflet was approved on 03/07/2018. Trademarks are owned by or licensed to the GSK group of companies. ©2018 GSK group of companies or its licensor. 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 03 July 2018.

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

QUALITATIVE AND QUANTITATIVE COMPOSITION

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

PHARMACEUTICAL FORM

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

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening. Augmentin is used in babies and children to treat the following infections:

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

Posology and Method of Administration

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

Adults and children weighing 40 kg or over

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

Children weighing less than 40 kg

All doses are worked out depending on the child's body weight in kilograms.

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

Patients with kidney and liver problems

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

How to give Augmentin

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

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	Volume of water to be added at reconstitution (ml)	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.

Advice/medical education

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

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

Contraindications

If children 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.

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.

Interactions

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive. Do not operate machinery unless you are feeling well.

Possible side effects

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

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)).

Reporting of side effects

If your child gets side effects talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.
By reporting side effects you can help provide more information about the safety of this medicine.

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.

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.

Manufactured by:

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France.
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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

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

QUALITATIVE AND QUANTITATIVE COMPOSITION: Each ml of suspension contains amoxicillin trihydrate equivalent to 40 mg and potassium clavulanate equivalent to 5.7 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 200 mg/28.5 mg/5 ml powder for oral suspension is a white to off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 70 ml of an off-white liquid mixture called a suspension. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening. Augmentin is used in babies and children to treat 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:** 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. 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. 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. **Instructions for reconstitution**: Check cap seal is intact before using. 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:** If children 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. If they have ever had liver problems or jaundice (yellowing of the skin) when taking an 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 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. **Contact a doctor immediately if your child gets** hepatitis, jaundice, caused by increases in the blood of bilirubin 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:, a severe reduction in the number of white blood cells, low number of red blood cells (hemolytic anemia), or crystals in urine. **Interactions**: Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. **Pregnancy, breast-feeding, and fertility:** If your child who is about to take this medicine is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Driving and using machines:** Augmentin can have side effects and the symptoms may make you unfit to drive. Do not operate machinery unless you are feeling well. **Possible side effects:** allergic reactions, inflammation of the large intestine, thrush, nausea, especially when taking high doses, and diarrhea (in children). **Overdosage:** If you give your child too much Augmentin, signs might include an upset stomach or convulsions. Talk to their doctor as soon as possible.Take the medicine bottle to show the doctor. **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. **Manufactured by:** Glaxo Wellcome Production, 53100 MAYENNE, France. This leaflet was approved on 28/02/2018. Trademarks are owned by or licensed to the GSK group of companies. **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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 28 February 2018.

Prescribing Information for Bahrain
Augmentin 312 mg/5 ml suspension
Co-amoxiclav (Amoxicillin trihydrate + potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

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

PHARMACEUTICAL FORM

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

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening. Augmentin is used in babies and children to treat the following infections:

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

Posology and Method of Administration

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

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 bodyweight 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.
- Recomended 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.

Instructions for reconstitution

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

Strength	Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral 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 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 a different medicine.

Conditions you need to look out for

Augmentin can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Augmentin, to reduce the risk of any problems.

Blood and urine tests

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

Augmentin contains aspartame and maltodextrin:

• Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

• Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine. Conditions you need to look out for Allergic reactions:

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

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

Inflammation of 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

• diarrhoea (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
• diarrhoea (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 (haemolytic anaemia)
• crystals in urine.

Overdosage

If you give your child too much Augmentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea) 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.

PHARMACEUTICAL DATA

List of Excipients

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

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.
Store in a dry place at 30°C or below.
Before reconstitution, keep tightly closed and store in a dry place at 30°C or below.
Once reconstituted, store in a refrigerator and use within 7 days.
Do not freeze.
Do not use this medicine after the expiry date 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.

Manufactured by:

Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France
This leaflet was approved on 27/04/2018.

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 mail box Gulf-KSA.Product-Complaints@gsk.com.
Prescribing information for Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 27 April 2018.

Abbreviated Prescribing Information for Bahrain
Augmentin 312 mg/5 ml suspension
Co-amoxiclav (Amoxicillin trihydrate + potassium clavulanate)

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 50 mg amoxicillin and potassium clavulanate equivalent to 12.5 mg of clavulanic acid. **PHARMACEUTICAL FORM:** Augmentin 312 mg/5 ml Suspension is an off-white powder supplied in a clear glass bottle. Once made up, the bottle contains 100 ml of an off-white liquid mixture called a suspension. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening. Augmentin is used in babies and children to treat 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:** 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. 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: 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 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. Shake the bottle well before each dose. **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. 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, breast-feeding and fertility:** If your child who is about to take this medicine is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine. **Driving and using machines:** Augmentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well. **Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them. **Very common side effects:** These may affect more than 1 in 10 people such as 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 (vomiting and diarrhea in children) take Augmentin with a meal. **Overdosage:** If you give your child too much Augmentin, talk to their doctor as soon as possible. Take the medicine bottle to show the doctor. **PHARMACEUTICAL DATA: List of Excipients:** Xanthan gum, hydroxypropyl methylcellulose, aspartame, silicon dioxide, colloidal silica, succinic acid, raspberry, orange, and golden syrup dry flavors. **Special Precautions for Storage:** Keep this medicine out of the sight and reach of children. Store in a dry place at 30°C or below. Before reconstitution, keep tightly closed and store in a dry place at 30°C or below. Once reconstituted, store in a refrigerator and use within 7 days. Do not freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of 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. **Manufactured by:** Manufacturer: Glaxo Wellcome Production, 53100 MAYENNE, France This leaflet was approved on 27/04/2018. **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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: 27 April 2018.

Prescribing Information for Bahrain
Augmentin™ 375 mg tablets
Amoxicillin trihydrate and potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 mg amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate).

PHARMACEUTICAL FORM

Film-coated tablet. White to off-white, oval-shaped tablets debossed with "Augmentin" on one side.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin™ is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Cystitis
- Pyelonephritis
- Cellulitis
- Animal bites
- Severe dental abscess with spreading cellulitis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and Method of Administration

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Augmentin that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below

The use of alternative presentations of Augmentin™ (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.

For adults and children ≥ 40 kg, this formulation of Augmentin™ provides a total daily dose of 750 mg amoxicillin/375 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid.

Treatment should not be extended beyond 14 days without review.

Adults and children ≥ 40 kg

One 250 mg/125 mg tablet taken three times a day.

Children < 40 kg

Augmentin 250 mg/125 mg film-coated tablets are not recommended in children < 40 kg.

Elderly

No dose adjustment is considered necessary.

Renal impairment

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

No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

Adults and children ≥ 40 kg

CrCl: 10-30 ml/min	250 mg/125 mg twice daily
CrCl < 10 ml /min	250 mg/125 mg once daily
Haemodialysis	Two doses of 250 mg/125 mg every 24 hours, plus two doses of 250 mg/125 mg during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased)

Children < 40 kg

In children < 40 kg with creatinine clearance less than 30 ml/min, the use of Augmentin presentations with amoxicillin to clavulanic acid ratio of 2:1 is not recommended, as no dose adjustments are available. In such patients, Augmentin formulations with amoxicillin to clavulanic acid ratio of 4:1 are recommended.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

Method of administration

Augmentin™ is for oral use.

Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/ clavulanic acid.

Contraindications

Amoxicillin-clavulanate is contra-indicated:

- in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins
- in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction.

Warnings and Precautions

Before initiating therapy with amoxicillin-clavulanate, 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. If an allergic reaction occurs, amoxicillin-clavulanate therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, i.v. steroids and airway management, including intubation may also be required. Amoxicillin-clavulanate 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. In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic

function is advisable during prolonged therapy. Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin-clavulanate 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. Amoxicillin-clavulanate should be used with caution in patients with evidence of hepatic dysfunction. In patients with renal impairment, the dosage should be adjusted according to the degree of impairment. 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. Amoxicillin-clavulanate Suspensions/Sachets/Chewable Tablets (where applicable), contain aspartame, which is a source of phenylalanine and so 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 amoxicillin-clavulanate may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid. 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 amoxicillin-clavulanate and allopurinol. In common with other antibiotics, amoxicillin-clavulanate 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 amoxicillin. 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, breast-feeding and fertility

Fertility

No Text.

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin-clavulanate 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 amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant.

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

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.Overdosage

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

Adults:

Very common	Diarrhoea
Common	Nausea, vomiting

Children:

Common	Diarrhoea, Nausea, vomiting

All populations:

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin-clavulanate 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+.

+This statement is core safety for the syrup, suspension and chewable tablet formulations.

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. 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+.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.

Children (additional statement):

These events have been very rarely reported in children.

All populations:

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

Overdosage

Symptoms and Signs

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Treatment

GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin-clavulanate can be removed from the circulation by haemodialysis.

Children (additional statement):

A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Drug abuse and dependence

Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound.

PHARMACEUTICAL DATA

List of Excipients

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

Incompatibilities

Not applicable.

Shelf-life

As indicated on the outer packaging.

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

Special Precautions for Storage

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

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

Use within 14 days of opening.

Nature and Contents of Container

Augmentin 375 mg Tablets supplied in a carton containing 20 tablets in blisters inside a desiccated pouch.

Manufactured by:

SmithKline Beecham Limited*

Worthing, United Kingdom

*Member of the GlaxoSmithKline group of companies

AUGMENTIN is a trademark of the GlaxoSmithKline group of companies.

GDS Version Number: 21

Version Date: 18 January 2013

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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Abbreviated Prescribing Information for Bahrain
Augmentin™ 375 mg tablets
Amoxicillin trihydrate and potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Each tablet contains 250 mg amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate). **PHARMACEUTICAL FORM:** Film-coated tablet. White to off-white, oval-shaped tablets debossed with "Augmentin" on one side. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin™ is indicated for the treatment of the following infections in adults and children with acute bacterial sinusitis (adequately diagnosed), cystitis, pyelonephritis, cellulitis, animal bites, and severe dental abscess with spreading cellulitis. **Posology and Method of Administration:** Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component. The dose of Augmentin that is selected to treat an individual infection should take into account the expected pathogens and their likely susceptibility to antibacterial agents, the severity and the site of the infection, and the age, weight and renal function of the patient. For adults and children ≥ 40 kg, this formulation of Augmentin™ provides a total daily dose of 750 mg amoxicillin/375 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid. Treatment should not be extended beyond 14 days without review. Adults and children ≥ 40 kg: One 250 mg/125 mg tablet taken three times a day. Children < 40 kg: Augmentin 250 mg/125 mg film-coated tablets are not recommended in children < 40 kg. Elderly: No dose adjustment is considered necessary. Renal impairment: Dose adjustments are based on the maximum recommended level of amoxicillin. No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min. Adults and children ≥ 40 kg with CrCl of 10-30 ml/min are given 250 mg/125 mg twice daily. Those with CrCl < 10 ml /min are given 250 mg/125 mg once daily, while those on haemodialysis are given two doses of 250 mg/125 mg every 24 hours, plus two doses of 250 mg/125 mg during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased). Children < 40 kg: In children < 40 kg with creatinine clearance less than 30 ml/min, the use of Augmentin presentations with amoxicillin to clavulanic acid ratio of 2:1 is not recommended, as no dose adjustments are available. In such patients, Augmentin formulations with amoxicillin to clavulanic acid ratio of 4:1 are recommended. Hepatic impairment: Dose with caution and monitor hepatic function at regular intervals. Method of administration: Augmentin™ is for oral use. Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/ clavulanic acid. **Contraindications:** Amoxicillin-clavulanate is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporin, and in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction. **Warnings and Precautions:** In general amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Before initiating therapy with amoxicillin-clavulanate, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. **Interactions:** Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with amoxicillin-clavulanate may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. 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, breast-feeding and fertility: Fertility:** No Text. **Pregnancy:** In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician. **Lactation:** Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant. **Adverse Reactions:** Common adverse events include mucocutaneous candidiasis, nausea, and vomiting. **Overdosage:** GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin-clavulanate can be removed from the circulation by haemodialysis. **PHARMACEUTICAL DATA: List of Excipients:** Each tablet contains magnesium stearate, sodium starch glycollate, colloidal silica, microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol and silicone oil. **Special Precautions for Storage:** Store in a dry place at 30°C or below. Store in the original package in order to protect from moisture. Use within 14 days of opening. **Nature and Contents of Container:** Augmentin 375 mg Tablets supplied in a carton containing 20 tablets in blisters inside a desiccated pouch. **Manufactured by:** SmithKline Beecham Limited* Worthing, United Kingdom. *Member of the GlaxoSmithKline group of companies. AUGMENTIN is a trademark of the GlaxoSmithKline group of companies. **GDS Version Number: 21. Version Date: 18 January 2013 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Prescribing Information for Bahrain
Augmentin™ 457mg/5 ml - Mixed fruit flavour
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Augmentin™ suspension 457 mg/5 ml contains 400 mg amoxicillin (as amoxicillin trihydrate) and 57 mg clavulanic acid (as potassium clavulanate) per 5 ml.

PHARMACEUTICAL FORM

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

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin™ is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community-acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and Method of Administration

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Augmentin™ that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below

The use of alternative presentations of Augmentin™ (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.

Adults and children ≥ 40 kg

For Augmentin™ suspension 457 mg/5 ml:

Children ≥ 40 kg should be treated with the adult formulations of Augmentin™.

Children < 40 kg

For Augmentin™ suspension 457 mg/5 ml:

For children < 40 kg, these formulations of Augmentin™ provides a maximum daily dose of 1000-2800 mg amoxicillin/143-400 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid. Children < 40 kg may be treated with Augmentin™ tablets, suspensions or paediatric sachets. The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.

Recommended doses:

- 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses;
- up to 70 mg/10 mg/kg/day given as two divided doses may be considered for some infections (such as otitis media, sinusitis and lower respiratory tract infections).

No clinical data are available for Augmentin™ 7:1 formulations regarding doses higher than 45 mg/6.4 mg per kg per day in children under 2 years.

There are no clinical data for Augmentin™ 7:1 formulations for patients under 2 months of age. Dosing recommendations in this population, therefore, cannot be made.

Elderly

No dose adjustment is considered necessary.

Renal impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

In patients with creatinine clearance less than 30 ml/min, the use of Augmentin™ presentations with amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose, adjustments are available.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

Method of administration

Augmentin™ is for oral use.

Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid.

Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation.

Shake to loosen powder, add water as directed, invert and shake.

Shake the bottle before each dose.

Contraindications

Amoxicillin-clavulanate is contra-indicated:

- in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins
- in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction.

Warnings and Precautions

Before initiating therapy with amoxicillin-clavulanate, 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. If an allergic reaction occurs, amoxicillin-clavulanate therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, i.v. steroids and airway management, including intubation, may also be required. Amoxicillin-clavulanate 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.
In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.
Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin-clavulanate 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.
Amoxicillin-clavulanate should be used with caution in patients with evidence of hepatic dysfunction.
In patients with renal impairment, the dosage should be adjusted according to the degree of impairment.
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.
Amoxicillin-clavulanate Suspensions/Sachets/Chewable Tablets (where applicable), contain aspartame, which is a source of phenylalanine and so 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 amoxicillin-clavulanate may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.
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 amoxicillin-clavulanate and allopurinol.
In common with other antibiotics, amoxicillin-clavulanate 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 amoxicillin.
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, breast-feeding and fertility

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin-clavulanate 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 amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant.

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

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	
Adults:	
Very common	Diarrhoea
Common	Nausea, vomiting
Children:	
Common	Diarrhoea, nausea, vomiting

All populations:

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin-clavulanate 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+.

+This statement is core safety for the syrup, suspension and chewable tablet formulations.

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.

Children (additional statement):

These events have been very rarely reported in children.

All populations

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.

Overdosage

Symptoms and Signs

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.

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

Treatment

GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance.

Amoxicillin-clavulanate can be removed from the circulation by haemodialysis.

Children (additional statement):

A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Drug abuse and dependence

Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound.

PHARMACEUTICAL DATA

List of Excipients

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

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 30°C.

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

Do not freeze.

Nature and Contents of Container

Clear, glass bottles with aluminium screw caps, containing an off-white dry powder. The Augmentin™ suspension 457 mg/5 ml 35 ml and 70 ml presentations may be supplied with a cup dosing device.

or

Single-dose sachets (Augmentin™ suspension 457 mg/5 ml only).

When reconstituted, an off-white suspension is formed.

Instructions for Use/Handling

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, add water to 2/3 of fill line level, invert and shake well, then top up with water exactly to the mark, invert and again shake well.

Strength	The volume of water to be added at reconstitution (ml)	The final volume of reconstituted oral suspension (ml)
200 mg/28.5 mg/5 ml	64	70
400 mg/57 mg/5 ml	62	70

Shake the bottle well before each dose.

Manufactured by:

SmithKline Beecham Limited*

Worthing, United Kingdom

*Member of the GlaxoSmithKline group of companies

AUGMENTIN is a trademark of the GlaxoSmithKline group of companies.

GDS Version Number: 21
Version Date: 18 January 2013
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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Abbreviated Prescribing Information for Bahrain
Augmentin™ suspension 457mg/5 ml - Mixed fruit flavour
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Augmentin™ suspension 457 mg/5 ml contains 400 mg amoxicillin (as amoxicillin trihydrate) and 57 mg clavulanic acid (as potassium clavulanate) per 5 ml. **PHARMACEUTICAL FORM:** Dry powder for reconstitution in water, at time of dispensing, to form an oral sugar-free suspension. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin™ is indicated in adults and children for the treatment of acute bacterial sinusitis (adequately diagnosed), acute otitis media, acute exacerbations of chronic bronchitis (adequately diagnosed), community-acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, bone and joint infections, in particular osteomyelitis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **Posology and Method of Administration:** Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component. The dose of Augmentin™ that is selected to treat an individual infection should take into account that the expected pathogens and their likely susceptibility to antibacterial agents, the severity and the site of the infection, and the age, weight and renal function of the patient. The use of alternative presentations of Augmentin™ (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary For adults and children ≥ 40 kg. For Augmentin™ suspension 457 mg/5 ml: Children ≥ 40 kg should be treated with the adult formulations of Augmentin™. For children < 40 kg, these formulations of Augmentin™ provides a maximum daily dose of 1000-2800 mg amoxicillin/143-400 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid. Children < 40 kg may be treated with Augmentin™ tablets, suspensions or paediatric sachets. The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review. Recommended doses: 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses; and up to 70 mg/10 mg/kg/day is given as two divided doses may be considered for some infections (such as otitis media, sinusitis and lower respiratory tract infections). Elderly: No dose adjustment is considered necessary. Renal impairment: No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min. In patients with creatinine clearance less than 30 ml/min, the use of Augmentin™ presentations with amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose, adjustments are available. Hepatic impairment: Dose with caution and monitor hepatic function at regular intervals. Method of administration: Augmentin™ is for oral use. Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid. Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation. Shake to loosen powder, add water as directed, invert and shake. Shake the bottle before each dose. **Contraindications:** Amoxicillin-clavulanate is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins, and in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction. **Warnings and Precautions:** Before initiating therapy with amoxicillin-clavulanate, 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. **Interactions:** Concomitant use of probenecid is not recommended. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. 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, breast-feeding and fertility: Pregnancy:** In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician. **Lactation:** Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant. **Ability to perform tasks that require judgement, motor or cognitive skills:** Adverse effects on the ability to drive or operate machinery have not been observed. **Adverse Reactions:** common side effects include mucocutaneous candidiasis, diarrhoea, nausea, and vomiting. **Overdosage:** GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin-clavulanate can be removed from the circulation by haemodialysis. **PHARMACEUTICAL DATA: List of Excipients:** Xanthan gum, hydroxypropylmethylcellulose, colloidal silica, succinic acid, silicon dioxide, raspberry, orange "1", orange "2", golden syrup dry flavours, aspartame. **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 30°C. Once reconstituted, the suspension must be stored in a refrigerator (2-8°C) and used within seven days. Do not freeze. **Nature and Contents of Container:** Clear, glass bottles with aluminium screw caps, containing an off-white dry powder. The AugmentinT™ suspension 457 mg/5 ml 35 ml and 70 ml presentations may be supplied with a cup dosing device. Or Single-dose sachets (Augmentin™ suspension 457 mg/5 ml only). When reconstituted, an off-white suspension is formed. **Instructions for Use/Handling:** Check cap seal is intact before using. Shake bottle to loosen powder, add water to 2/3 of fill line level, invert and shake well, then top up with water exactly to the mark, invert and again shake well. Shake the bottle well before each dose. **Manufactured by:** SmithKline Beecham Limited*. Worthing, United Kingdom. *Member of the GlaxoSmithKline group of companies. AUGMENTIN is a trademark of the GlaxoSmithKline group of companies. **GDS Version Number: 21. Version Date: 18 January 2013. 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Prescribing Information for Bahrain
AUGMENTIN™ 625 mg tablets
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Augmentin™ 625 mg tablets: Each film-coated tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate).

PHARMACEUTICAL FORM

Augmentin™ 625 mg tablets: Film-coated tablet. White to off-white, oval film-coated tablets debossed with 'AC' and a score line on one side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin™ is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community-acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis
- Bone and joint infections, in particular, osteomyelitis

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and Method of Administration

Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component.

The dose of Augmentin™ that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents.
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below.

The use of alternative presentations of Augmentin™ (e.g. those that provide higher doses of amoxicillin and/or different ratios of amoxicillin to clavulanic acid) should be considered as necessary.

For adults and children ≥ 40 kg, these formulations of Augmentin™ provide a total daily dose of 1500 mg amoxicillin/375 mg clavulanic acid, when administered as recommended below. For children < 40 kg, these formulations of Augmentin™ provide a maximum daily dose of 2400 mg amoxicillin/600 mg clavulanic acid, when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid.

The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review.

Adults and children ≥ 40 kg

One 500 mg/125 mg dose taken three times a day.

Children < 40 kg

20 mg/5 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses.

Children may be treated with Augmentin™ tablets, suspensions or paediatric sachets. Children aged 6 years and below or weighing less than 25 kg should preferably be treated with Augmentin suspension or paediatric sachets.

For Augmentin™ 625 mg tablets:

As the tablets cannot be divided, children weighing less than 25 kg must not be treated with Augmentin tablets.

The table below presents the received dose (mg/kg body weight) in children weighing 25 kg to 40 kg upon administering a single 500/125 mg tablet.

Body weight [kg]	40	35	30	25	Single dose recommended [mg/kg body weight]
Amoxicillin [mg/kg body weight] per single dose (1 film-coated tablet)	12.5	14.3	16.7	20.0	6.67 – 20
Clavulanic acid [mg/kg body weight] per single dose (1 film-coated tablet)	3.1	3.6	4.2	5.0	1.67 - 5

No clinical data are available on doses of Augmentin™ 4:1 formulations higher than 40 mg/10 mg/kg per day in children under 2 years.

Elderly

No dose adjustment is considered necessary.

Renal impairment

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

No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

Adults and children ≥ 40 kg

CrCl: 10-30 ml/min	500 mg/125 mg twice daily
CrCl < 10 ml /min	500 mg/125 mg once daily
Haemodialysis	500 mg/125 mg every 24 hours, plus 500 mg/125 mg during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased)

Children < 40 kg

CrCl: 10-30 ml/min	15 mg/3.75 mg/kg twice daily (maximum 500 mg/125 mg twice daily).
CrCl < 10 ml/min	15 mg/3.75 mg/kg as a single daily dose (maximum 500 mg/125 mg).
Haemodialysis	15 mg/3.75 mg/kg per day once daily. Prior to haemodialysis 15 mg/3.75 mg/kg. In order to restore circulating drug levels, 15 mg/3.75 mg per kg should be administered after haemodialysis.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

Method of administration

Augmentin™ is for oral use.

Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid.

Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation.

Contraindications

Amoxicillin-clavulanate is contra-indicated

- in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins
- in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction.

Warnings and Precautions

Before initiating therapy with amoxicillin-clavulanate, 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. If an allergic reaction occurs, amoxicillin-clavulanate therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, i.v. steroids and airway management, including intubation, may also be required.

Amoxicillin-clavulanate 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.

In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin-clavulanate 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.

Amoxicillin-clavulanate should be used with caution in patients with evidence of hepatic dysfunction.

In patients with renal impairment, the dosage should be adjusted according to the degree of impairment.

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.

Amoxicillin-clavulanate Suspensions/Sachets/Chewable Tablets (where applicable), contain aspartame, which is a source of phenylalanine and so 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 amoxicillin-clavulanate may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.

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 amoxicillin-clavulanate and allopurinol.

In common with other antibiotics, amoxicillin-clavulanate 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 amoxicillin. 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

Fertility

No Text.

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin-clavulanate 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 amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant.

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

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	
Adults:	
Very common	Diarrhoea
Common	Nausea, vomiting
Children:	
Common	Diarrhoea, nausea, vomiting

All populations:

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin-clavulanate 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+.

+This statement is core safety for the syrup, suspension and chewable tablet formulations.

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.

Children (additional statement):

These events have been very rarely reported in children.

All populations

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.

Overdosage

Symptoms and Signs

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.

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

Treatment

GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance.

Amoxicillin-clavulanate can be removed from the circulation by haemodialysis.

Children (additional statement):

A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Drug abuse and dependence

Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound.

PHARMACEUTICAL DATA

List of Excipients

Augmentin™ 625 mg tablets:

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

Incompatibilities

None.

Shelf life

Augmentin™ 625 mg tablets:

As indicated on the outer packaging.

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

Special precautions for storage

Store in a dry place at 30°C or below.
Augmentin™ 625 mg tablets:
Store in the original package in order to protect from moisture.
Use within 14 days of opening.

Nature and Contents of Container

Augmentin™ 625 mg tablets: A carton containing 20 tablets in blisters inside a desiccated pouch.
Not all pack sizes may be marketed.

Instructions for Use/Handling

Augmentin™ 625 mg tablets: None

Manufactured by:

SmithKline Beecham Limited*
Worthing, United Kingdom
*Member of the GlaxoSmithKline group of companies
AUGMENTIN is a trademark of the GlaxoSmithKline group of companies.

GDS Version Number: 21
Version Date: 18 January 2013

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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013.

Abbreviated Prescribing Information for Bahrain
AUGMENTIN™ 625 mg tablets
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: Augmentin™ 625 mg tablets: Each film-coated tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate). **PHARMACEUTICAL FORM:** Augmentin™ 625 mg tablets: Film-coated tablet. White to off-white, oval film-coated tablets debossed with 'AC' and a score line on one side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin™ is indicated in adults and children for the treatment of acute bacterial sinusitis (adequately diagnosed), acute otitis media, acute exacerbations of chronic bronchitis (adequately diagnosed), community-acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, and bone and joint infections, in particular, osteomyelitis. **Posology and Method of Administration:** For adults and children ≥ 40 kg, these formulations of Augmentin™ provide a total daily dose of 1500 mg amoxicillin/375 mg clavulanic acid when administered. For children < 40 kg, these formulations of Augmentin™ provide a maximum daily dose of 2400 mg amoxicillin/600 mg clavulanic acid. If it is considered that a higher daily dose of amoxicillin is required, it is recommended that another preparation of Augmentin™ is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid. The duration of therapy should be determined by the response of the patient. Some infections (e.g. osteomyelitis) require longer periods of treatment. Treatment should not be extended beyond 14 days without review. Adults and children ≥ 40 kg: One 500 mg/125 mg dose taken three times a day. Children < 40 kg: 20 mg/5 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses. Children may be treated with Augmentin™ tablets, suspensions or paediatric sachets. Children aged 6 years and below or weighing less than 25 kg should preferably be treated with Augmentin suspension or paediatric sachets. For Augmentin™ 625 mg tablets: As the tablets cannot be divided, children weighing less than 25 kg must not be treated with Augmentin tablets. Elderly: No dose adjustment is considered necessary. Renal impairment: Dose adjustments are based on the maximum recommended level of amoxicillin. No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 ml/min. Hepatic impairment: Dose with caution and monitor hepatic function at regular intervals. Method of administration: Augmentin™ is for oral use. Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid. Therapy can be started parenterally according to the prescribing information of the IV-formulation and continued with an oral preparation. **Contraindications:** Amoxicillin-clavulanate is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins, and in patients with a previous history of amoxicillin-clavulanate-associated jaundice/hepatic dysfunction. **Warnings and Precautions:** Before initiating therapy with amoxicillin-clavulanate, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. In general, amoxicillin-clavulanate is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. **Interactions:** Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. 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 amoxicillin-clavulanate and allopurinol. **Pregnancy and Lactation: Fertility:** No Text. **Pregnancy:** In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician. **Lactation:** Amoxicillin-clavulanate 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 known detrimental effects for the breast-fed infant. **Ability to perform tasks that require judgement, motor or cognitive skills:** Adverse effects on the ability to drive or operate machinery have not been observed. **Adverse Reactions:** Common adverse reactions: Mucocutaneous candidiasis, nausea, vomiting. Common adverse reactions in children: Diarrhoea, nausea, vomiting. **Overdosage: Treatment:** GI symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin-clavulanate can be removed from the circulation by haemodialysis. **Children (additional statement):** A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying. **Drug abuse and dependence:** Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound. **PHARMACEUTICAL DATA: List of Excipients:** Augmentin™ 625 mg tablets: Each tablet contains magnesium stearate, sodium starch glycollate, colloidal silica, microcrystalline cellulose, titanium dioxide (E171), hydroxypropyl methylcellulose, polyethylene glycol and silicone oil. **Shelf life:** Augmentin™ 625 mg tablets: As indicated on the outer packaging. Tablets in desiccated pouch packs should be used within 14 days of opening. **Special precautions for storage:** Store in a dry place at 30°C or below. Augmentin™ 625 mg tablets: Store in the original package in order to protect from moisture. Use within 14 days of opening.. Augmentin™ 625 mg tablets: A carton containing 20 tablets in blisters inside a desiccated pouch. Not all pack sizes may be marketed. Instructions for Use/Handling Augmentin™ 625 mg tablets: None. **Manufactured by:** SmithKline Beecham Limited* Worthing, United Kingdom *Member of the GlaxoSmithKline group of companies**.** AUGMENTIN is a trademark of the GlaxoSmithKline group of companies. GDS Version Number: 21 Version Date: 18 January 2013 **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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorisation: 18 January 2013

Prescribing Information for Bahrain
Augmentin ES - 600 mg/42.9 mg/5 ml powder for oral suspension
Amoxicillin/clavulanic acid

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.

− Always shake the bottle well before each dose.

− Give it at the start of a meal or slightly before.

− Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

− Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

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.

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

Advice/medical education

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

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

Contraindications

Do not give your child Augmentin:

− if they are allergic to amoxicillin, clavulanic acid, or any of the other ingredients of this medicine

− if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat

− if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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

Warnings and Precautions

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

− they have glandular fever

− they are being treated for liver or kidney problems

− they are not urinating regularly.

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

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child may be given a different strength of Augmentin or different medicine.

Conditions you need to look out for

Augmentin can make some existing conditions worse or cause serious side effects. These include allergic reactions, convulsions, and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Augmentin to reduce the risk of any problems.

Blood and urine tests

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

Important information on some Augmentin components

Augmentin contains aspartame (E951) which is a source of phenylalanine. This may be harmful to children born with "phenylketonuria".

Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interactions

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

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

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

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

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

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

Pregnancy, lactation, and fertility

If your child who is about to take Augmentin is pregnant or breast-feeding, please tell your doctor or pharmacist.

Talk to your doctor or pharmacist before taking any medicinal product.

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.

Overdosage
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.

PHARMACEUTICAL DATA

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

Storage
Keep this medicine out of the sight and reach of children.
Powder for oral suspension:
Store in the original container to protect from moisture.
Do not store above 30°C.
Do not use Augmentin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Liquid suspension:
Store in a refrigerator (2°C-8°C). Do not freeze.
Once made up, the suspension should be used within 10 days.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.
These measures will help you to protect the environment.

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

This leaflet was last revised in 03/2015

Manufactured by:
GlaxoWellcome Production*, Mayenne, France
*Member of the GlaxoSmithKline group of companies

Reporting of side effects
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Augmentin ES - 600 mg/42.9 mg/5 ml powder for oral suspension
Amoxicillin/clavulanic acid

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 used in babies and children to treat middle ear infections and 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. Always shake the bottle well before each dose. Give it at the start of a meal or slightly before. Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not give your child Augmentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor. **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. 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. **Instructions for reconstitution:** Check cap seal is intact before using. Shake bottle to loosen powder. Add the volume of water (90 ml to get a final volume of reconstituted oral suspension). 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. **Contraindications:** Do not give your child Augmentin, if they are allergic to amoxicillin, clavulanic acid, 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 your doctor or pharmacist before giving Augmentin. **Warnings and Precautions:** Talk to your doctor or pharmacist before giving Augmentin to your child if they have glandular fever, they are being treated for liver or kidney problems, or if 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. 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. **Pregnancy, lactation, and fertility:** If your child who is about to take Augmentin is pregnant or breast-feeding, please tell your doctor or pharmacist. Talk to your doctor or pharmacist before taking any medicinal product. **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:** 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, and diarrhea (in children). Common side effects may affect **up to 1 in 10** people. **Overdosage:** If you give your child too much Augmentin, talk to your doctor as soon as possible. Take the medicine bottle to show the doctor. **PHARMACEUTICAL DATA: List of Excipients:** Aspartame (E951), xanthan gum, colloidal hydrated silicon, colloidal anhydrous silica, artificial strawberry cream flavor, and water. **Storage:** Keep this medicine out of the sight and reach of children. Powder for oral suspension: Store in the original container to protect from moisture. Do not store above 30°C. Do not use Augmentin after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Liquid suspension: Store in a refrigerator (2°C-8°C). Do not freeze. Once made up, the suspension should be used within 10 days. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help you to protect the environment. **Manufacturer:** *AUGMENTIN ES* and *AUGMENTIN* are trademarks of the GlaxoSmithKline group of companies This leaflet was last revised in 03/2015. Manufactured by: GlaxoWellcome Production*, Mayenne, France *Member of the GlaxoSmithKline 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: March 2015.

Prescribing Information for Bahrain
Augmentin 62.5 mg/ml Infant Drops
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredients are: Amoxicillin Trihydrate / Potassium Clavulanate, 1 ml of prepared suspension contains 57.4 mg amoxicillin trihydrate equivalent to 50 mg amoxicillin, and 15 mg potassium clavulanate, equivalent to 12.5 mg clavulanic acid.

PHARMACEUTICAL FORM

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

CLINICAL PARTICULARS

Therapeutic Indications

Augmentin is an antibiotic that works by killing bacteria that cause infections. It contains two different active ingredients, amoxicillin, and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes become inactive. The second active ingredient (clavulanic acid) prevents that
Augmentin is used in the treatment of the following infections in infants and children:

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

Posology and Method of Administration

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

Adults and children weighing 40 kg and over

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

Children weighing less than 40 kg

All doses are calculated based on the bodyweight of the child in kilograms.

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

Patients with kidney or liver problems

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

Instructions for use:

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

Instructions for reconstitution

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

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

Shake the bottle well before each use.

Advice/medical education

Antibiotics are used to treat bacterial infections. They are ineffective against viral infections.
Sometimes a bacterial infection does not respond to antibiotic treatment. One of the most common reasons for this is that the bacteria that cause infectious disease are resistant to the antibiotic used. This means that they can survive and even multiply despite the antibiotic.
Bacteria can become resistant to antibiotics for many different reasons. Cautious use of antibiotics can help reduce the risk of bacteria becoming resistant.
If your doctor prescribes antibiotic treatment, it is only for the purpose of treating your current case. The following advice will help to prevent the emergence of resistant bacteria that may inhibit the action of the antibiotic.
1. It is very important that you take the antibiotic at the right dose, at the right times, and for the right duration. Read the instructions on the label and ask your doctor or pharmacist if you do not understand anything.
2. You should not take an antibiotic if it was not specifically prescribed for you and you should only use it for the treatment of the infection for which it was prescribed.
3. You should not take any antibiotics that have been prescribed for other people, even if they had a similar infection.
4. You should not give antibiotics that you have been prescribed to other people.
5. If you have any of the antibiotics left after stopping treatment as directed by your doctor, you should take the unused antibiotic to a pharmacy for proper disposal.

Contraindications

You should not use Augmentin for your child in the following cases:

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

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

Warnings and Precautions

Please talk to your doctor, pharmacist, or a nurse before giving Augmentin to your child if your child:
• has Pfeiffer's glandular fever
• is being treated from liver or kidney problems
• has irregular water levels disorder.
Talk to your doctor or pharmacist before using Augmentin if you are not sure whether any of these cases apply to your child.
In certain cases, your doctor may determine the type of bacteria that causes your child infection. Depending on the results, your child may have a different strength of Augmentin or another medicine.
Augmentin contains aspartame and maltodextrin
• Augmentin contains aspartame (E 951) as a source of phenylalanine and may be harmful to children born with a condition called phenylketonuria.
• Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to certain sugars, contact your doctor before using this medicine.

Conditions you need to look out for

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

Blood and urine tests

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

Interactions

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

Pregnancy, lactation, and fertility

If your child is likely to be pregnant, nursing, suspected of being pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Effects on Ability to Drive and Use Machines

Augmentin may cause side effects and these symptoms may affect your ability to drive.
Do not drive a vehicle or operate machines if you do not feel comfortable.

Adverse Reactions

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur when taking this medicine.

Conditions you need to look out for

Allergic reaction:
• Skin rash
• Inflammation of blood vessels (vasculitis), which may manifest in red or purple raised spots on the skin, but can also affect other areas of the body
• Fever, joint pain, enlarged lymph nodes in the neck, armpits, or groin
• Swelling, sometimes on the face or throat (angioedema) causing breathing problems
• Collapse.
Contact a doctor immediately if any of these symptoms occur to your child. Stop taking Augmentin.

Inflammation of the large intestine

Inflammation of the large intestine that causes watery diarrhea, usually with blood and mucus, stomach pain, and/or fever.
Ask your doctor for advice as soon as possible if you experience these symptoms with your child.

Very common side effects
• In more than 1 person in 10
• Diarrhea (in adults).

Common side effects

1 to 10 users out of 100
• Fungal infection (Candida - yeast infection in the area of vagina, mouth, or skin folds)
• Nausea, especially when taking high doses
Give Augmentin with a meal if this is applied
• Vomiting
• Diarrhea (in children).

Uncommon side effects

1 to 10 users out of 1,000
• Skin rash, itching
• Loftier itchy rash (wheals)
• Upset stomach
• Dizziness
• Headache.
Uncommon side effects that may show up in blood tests:
• Increase of some substances (enzymes) produced by the liver as an indication of liver damage.
Rare side effects
1 to 10 people out of 10,000
• Skin rash, possibly with blisters that looks like small targets (a central dark spot with surrounding paler area and a dark ring around - erythema multiforme)
Contact a doctor urgently if this side effect occurred to your child.
Rare side effects that may show up in blood tests:
• Low number of cells involved in blood clotting

• Low number of white blood cells.

Frequency not known

Frequency cannot be estimated from the available data.

• Allergic reactions (see above)
• Inflammation of the large intestine (see above)
• Inflammation of the meninges (aseptic meningitis)
• Serious skin reactions:

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

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

• Inflammation of the liver (Hepatitis)
• Jaundice caused by an increase in bilirubin (a substance produced by the liver) in the blood, which can cause yellowing of your child's skin and white-eye areas
• Inflammation of renal tubules
• delaying blood clotting
• hyperactivity
• Seizures (in people taking high doses of Augmentin or having kidney problems)
• Black, hairy-looking tongue
• Discoloration of teeth (in children), usually can be removed by brushing.

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

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

Report 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.

Overdosage

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

If you forget to take Augmentin

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

If your child stops taking Augmentin

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

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

PHARMACEUTICAL DATA

List of Excipients

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

* It contains maltodextrin.

Storage

Store medicinal products out of reach of children.

Dry powder

Store in the original package to protect from moisture.

Store at or below 30°C.

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

Prepared suspension

Store in a refrigerator (2-8°C).

Do not freeze.

The prepared suspension should be used within 7 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Manufacturer

Glaxo Wellcome Production*, 53100 Mayenne, France

*member of GSK group of companies.

This package leaflet was revised last in December 2018.

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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: December 2018.

Abbreviated Prescribing Information for Bahrain
Augmentin 62.5 mg/ml Infant Drops
Amoxicillin trihydrate - Potassium clavulanate

QUALITATIVE AND QUANTITATIVE COMPOSITION: The active ingredients are: Amoxicillin Trihydrate / Potassium Clavulanate, 1 ml of prepared suspension contains 57.4 mg amoxicillin trihydrate equivalent to 50 mg amoxicillin, and 15 mg potassium clavulanate, equivalent to 12.5 mg clavulanic acid. **PHARMACEUTICAL FORM;** Augmentin 62.5 mg/ml infant drops are a cream-colored powder that is in a clear glass bottle. After preparation, the bottle contains 20 ml of a cream-colored mixture, called a suspension. **CLINICAL PARTICULARS: Therapeutic Indications:** Augmentin is used in infants and children in the treatment of otitis media infections and infections of the paranasal sinuses, respiratory 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:** This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice. **Children weighing less than 40 kg:** All doses are calculated based on the bodyweight of the child in kilograms. The recommended dose - 20 mg/5 mg (Amoxicillin trihydrate/Potassium clavulanate) to 60 mg/15 mg (Amoxicillin trihydrate/Potassium clavulanate) per kilogram of the body weight per day given in three divided doses. **Patients with kidney or liver problems:** If your child has kidney problems, the dose may be reduced. A different strength or different medicine may be chosen by your doctor, and if your child has liver problems, blood tests may be more frequent to monitor liver function. **Instructions for use:** Always shake the bottle well before each dose, take it with a meal, and take the doses evenly throughout the day with a gap of at least 4 hours. Do not use 2 doses within 1 hour. Do not use Augmentin for your child for more than 2 weeks. Visit your doctor again if your child does not feel better. **Instructions for reconstitution:** Before using, check that the cap's seal is intact. Shake the bottle to loosen the powder. Add the indicated amount of water (18 ml of water to prepare a final volume of 20 ml), turn the bottle over, and shake well. Using the dosing syringe, 18 ml of water (3 x 5 ml and 1 x 3 ml) can be measured. Alternatively, shake the bottle to loosen the powder and then fill the bottle with water just below the mark on the bottle or label, turn it over, and shake well. Then fill up to exactly this mark with water, turn it over and shake well again. Shake the bottle well before each use. **Contraindications:** You should not use Augmentin for your child if your child is allergic to amoxicillin, clavulanic acid, penicillin, or any other ingredients of this medicine, or if your child has ever had a severe allergic reaction to any other antibiotic. This may have been a rash or swelling of the face or throat, or if your child has ever had liver problems or jaundice (yellowing of the skin) while taking an antibiotic. **Warnings and Precautions:** Please talk to your doctor, pharmacist, or nurse before giving Augmentin to your child if your child has Pfeiffer's glandular fever, is being treated from liver or kidney problems, or has irregular water levels disorder. Augmentin contains aspartame (E 951) as a source of phenylalanine and may be harmful to children born with a condition called phenylketonuria. Augmentin contains maltodextrin (glucose). If you have been told by your doctor that your child has an intolerance to certain sugars, contact your doctor before using this medicine. **Conditions you need to look out for:** Augmentin can make some existing conditions worse, or lead to serious side effects. These include allergic reactions, seizures, and inflammation of the large intestine. You must look out for certain symptoms while you are giving your child "Augmentin", in order to reduce the risk of side effects. **Blood and urine tests:** If your child has blood tests (such as a red blood cell test or determination of liver function) or urine tests (for glucose), tell your doctor or nurse that your child takes Augmentin. This is necessary because Augmentin can influence the results of these tests. **Interactions:** Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. **Pregnancy, lactation, and fertility:** If your child is likely to be pregnant, nursing, suspected of being pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. **Effects on Ability to Drive and Use Machines:** Augmentin may cause side effects and these symptoms may affect your ability to drive. Do not drive a vehicle or operate machines if you do not feel comfortable. **Adverse Reactions:** Like all medicines, this medicine can cause side effects, although not everybody gets them. **Overdosage:** If you have used too much Augmentin for your child, he/she may experience stomach problems (nausea, vomiting, or diarrhea) or seizures. Contact your doctor as soon as possible. Take the medicine bottle with you and show it to the doctor. **PHARMACEUTICAL DATA: List of Excipients:** Aspartame (E 951), xanthan gum, silica, fumed silica, succinic acid, hypromellose, orange flavor 1* & 2*, raspberry flavor *, and gold syrup flavor. **Storage:** Store medicinal products out of reach of children. **Dry powder:** Store in the original package to protect from moisture. Store at or below 30°C. Do not use this medicine after the expiry date which is stated on the outer carton after "EXP". The expiry date refers to the last day of the specified month. **Prepared suspension:** Store in a refrigerator (2-8°C). Do not freeze. The prepared suspension should be used within 7 days. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. **Manufacturer:** Glaxo Wellcome Production, 53100 Mayenne, France (a member of GSK group of companies). This package leaflet was revised last in December 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 Bahrain. Prepared September 2020 from the summary of product characteristics version with Date of first authorization: December 2018.