AUGMENTIN BD SF

SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE:

AUGMENTIN BD SF Powder for Suspension Forte

Amoxicillin 400,0 mg/Clavulanic acid 57,0 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Powder for suspension forte (7:1 formulation), when reconstituted according to instructions each 5 mL contains amoxicillin trihydrate BP equivalent to 400,0 mg amoxicillin and potassium clavulanate equivalent to 57,0 mg clavulanic acid.

Sugar-free.

Contains sweetener – each 5 mL contains 12,5 mg aspartame

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Off-white powder for reconstitution to an off-white suspension with an orange/raspberry flavour.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:

AUGMENTIN formulations are indicated for the treatment of infections caused by amoxicillin-resistant organisms producing β-lactamases sensitive to clavulanic acid:

- Upper respiratory tract infections, such as sinusitis, otitis media, recurrent tonsillitis caused by *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* and *Streptococcus pyogenes* sensitive to AUGMENTIN

- Lower respiratory tract infections, such as acute exacerbations of chronic bronchitis and bronchopneumonia. (caused by *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* and *Streptococcus pyogenes)* sensitive to AUGMENTIN
- Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis caused by *Enterobacteriaceae* (mainly *Escherichia coli*), *Staphylococcus saprophyticus* and *Enterococcus* species and gonorrhoea caused by penicillin susceptible *Neisseria gonorrhoeae* sensitive to AUGMENTIN
- Skin and soft tissue infections caused by methicillin susceptible *Staphylococcus aureus*, *Streptococcus pyogenes* and *Bacteroides* species.

AUGMENTIN formulations will also be effective in the treatment of infections caused by amoxicillin-sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

4.2 Posology and method of administration:

Posology:

General Information:

For infections caused by amoxicillin-sensitive organisms the dosage is that approved for amoxicillin as the clavulanic acid component does not contribute to the therapeutic effect.

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

Children 2-12 years:

The dose of AUGMENTIN BD in children is 28,6 - 51,4 mg/kg/day of the 7 parts amoxicillin, 1 part clavulanic acid preparations (which corresponds to a daily dosage of the equivalent of 25 - 45 mg/kg of amoxicillin and 3,6 - 6,4 mg/kg of clavulanic acid) to be taken in divided doses every twelve hours, at the start of a meal.

	7 : 1 Formulation

Directions for use	In divided doses, twice daily (every 12 hours), at the start of a meal
Lower dose (mg/kg/day)	25/3,6 - 45/6,4
Higher dose (mg/kg/day)	45/6,4 - 70/10

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

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

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

Dosage Guide:

AMOXICILLIN-SENSITIVE ORGANISMS

PRODUCT	**Upper Respiratory Tract Infections**	**Lower Respiratory Tract Infections**	**Urinary Tract Infections**	**Skin & Soft Tissue Infections**
AUGMENTIN BD SF 22-40 kg (7-12 years)	5-10 mL [1)] 12 hourly	5-10 mL[1)] 12 hourly	5-10 mL [1)] 12 hourly	5-10 mL [1)] 12 hourly

AMOXICILLIN-RESISTANT ORGANISMS

PRODUCT	UPPER RESPIRATORY TRACT INFECTIONS (otitis media) *H. influenzae* *H. para influenzae*	LOWER RESPIRATORY TRACT INFECTIONS (bronchitis) *H. influenzae* *H. para influenzae*	URINARY TRACT INFECTIONS *E. coli* *Klebsiella pneumoniae*	SKIN & SOFT TISSUE INFECTIONS *Staphylococcus aureus*
AUGMENTIN BD SF 22-40 kg (7-12 years)	5-10 mL [1)] 12 hourly	5-10 mL [1)] 12 hourly	5-10 mL [1)] 12 hourly	5-10 mL [1)] 12 hourly

1)To correspond to a dosage of 51,4 mg/kg/day

Children aged 2 months to 2 years:

Children under 2 years should be dosed according to body weight.

Augmentin BD suspensions are not recommended for children under 2 months of age, due to immature renal function, the dose would need to be adjusted according to the amoxicillin content. However, with high amoxicillin/clavulanate ratios, this might lead to reduced doses of clavulanate and such doses have not been studied in this patient group.

Special populations:

Impaired renal function:

Both amoxicillin and clavulanic acid are excreted by the kidneys and the serum half-life of each, but particularly of amoxicillin, increases in patients with renal failure. Therefore, the

dose may need to be reduced or the dosing interval extended. Dosage adjustments are based on the maximum recommended level of amoxicillin. The following schedule is proposed:

Mild impairment	***Moderate impairment***	***Severe impairment***
Creatinine clearance greater than 30 mL/minute	Creatinine clearance 10 to 30 mL/minute	Creatinine clearance less than 10 mL/minute
No change in dosage.	15/3,75 mg/kg given 12 hourly.	15/3,75 mg/kg given as a single daily dose.
	Maximum amoxicillin dose: 30 mg/kg/day.	Maximum amoxicillin dose: 15 mg/kg/day.

AUGMENTIN BD suspensions are NOT recommended for children with a creatinine clearance of less than 30 mL/min.

No dosage recommendations can be made for premature infants.

Haemodialysis decreases serum concentrations of both amoxicillin and clavulanic acid and an additional dose should be administered at the end of dialysis.

Paediatric population:

Refer to section 4.2.

Method of administration:

AUGMENTIN Suspensions should be taken immediately before a meal.

Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.

For instructions on reconstitution of the product before administration, see section 6.6.

4.3 Contraindications:

Hypersensitivity to penicillins, amoxicillin and cephalosporins or other ingredients of AUGMENTIN.

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

Safety in children under 2 months of age has not been established.

4.4 Special warnings and precautions for use:

Serious and occasionally fatal hypersensitivity reactions including anaphylaxis and severe cutaneous adverse reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity, who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with AUGMENTIN, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, AUGMENTIN should be discontinued and the appropriate alternative therapy instituted. Serious anaphylactic reactions require emergency treatment with epinephrine (adrenaline).

Since AUGMENTIN contains amoxicillin, an aminopenicillin, it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of morbilliform rash if amoxicillin is used. AUGMENTIN should be avoided if infectious mononucleosis is suspected.

Changes in liver function tests have been observed in some patients receiving AUGMENTIN. Hepatic function should be monitored at regular intervals. Transient hepatitis and cholestatic jaundice have been reported. AUGMENTIN should be used with caution in patients with evidence of hepatic dysfunction.

In patients with renal impairment, dosages should be adjusted according to the degree of impairment (see section 4.2).

Prolonged use may also 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.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Aerobacter, Pseudomonas* or *Candida*), AUGMENTIN should be discontinued and/or appropriate therapy instituted.

Abnormal prolongation of prothrombin time (increased international normalised ratio (INR)) has been reported 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.

In patients with reduced urine output, crystalluria has been observed 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 (refer to section 4.9).

The use of this antibiotic may lead to the selection of resistant strains of organisms and sensitivity testing should, therefore, be carried out whenever possible, to demonstrate the appropriateness of therapy.

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

Susceptibility to AUGMENTIN will vary with geography and time. Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy.

AUGMENTIN should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxicillin induced skin rashes.

AUGMENTIN suspensions contain aspartame and should be used with caution in patients with phenylketonuria.

4.5 Interaction with other medicines and other forms of interaction:

Probenecid decreases the renal tubular secretion of amoxicillin but does not affect clavulanic acid excretion. Concomitant use with AUGMENTIN may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

The concomitant administration of allopurinol and ampicillin could substantially increase the incidence of skin rashes in patients receiving both agents as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients. There is no data on AUGMENTIN and allopurinol administered concomitantly.

No information is available about the concurrent use of AUGMENTIN and alcohol. However, the ingestion of alcohol whilst being treated with some other β-lactam antibiotics has precipitated a disulfiram like reaction in some patients. Therefore, the ingestion of alcohol should be avoided during and for several days after treatment with AUGMENTIN.

AUGMENTIN may affect the gut flora, leading to lower oestrogen re-absorption and reduced efficacy of combined oral contraceptives.

In the literature there are rare cases of increased INR in patients maintained on warfarin and prescribed a course of amoxicillin. If co-administration 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 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 pre-dose level may not accurately represent changes in overall MPA exposure

4.6 Fertility, pregnancy and lactation:

Pregnancy:

Safety in pregnancy has not been established.

In women with pre-term, premature rupture of the CR foetal membrane (pPROM), it was reported that a prophylactic treatment with amoxicillin-clavulanate may be associated with an increased risk of necrotising enterocolitis in neonates.

Breastfeeding:

Amoxicillin is excreted in breast milk. There is no data on the excretion of clavulanic acid in human milk. Mothers on treatment with AUGMENTIN should not breastfeed their infants.

4.7 Effects on ability to drive and use machines:

No negligible influence.

4.8 Undesirable effects:

Data from large clinical trials was 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.

Clinical trial data:

The following convention has been used for the classification of frequency:

very common ≥1/10

common ≥1/100 to <1/10

uncommon ≥1/1000 to <1/100

rare ≥1/10,000 to <1/1000

very rare <1/10,000.

Infections and infestations:

Common: Mucocutaneous candidiasis (including vaginitis, stomatitis, glossitis)

Blood and lymphatic system disorders:

Rare: reversible leucopenia (including neutropenia) and thrombocytopenia

Nervous system disorders:

Uncommon: Dizziness, headache.

Gastrointestinal disorders:

Common: Diarrhoea, nausea, vomiting

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking AUGMENTIN at the start of a meal.

Uncommon: Indigestion, gastritis.

Hepatobiliary disorders:

Uncommon: A moderate rise in AST and/or ALT has been noted in patients treated with AUGMENTIN.

Skin and subcutaneous tissue disorders:

Uncommon: Skin rash, pruritus, urticaria.

Rare: Erythema multiforme.

Side effects reported from post-marketing spontaneous reports:

Blood and lymphatic system disorders:

Reversible agranulocytosis, haemolytic anaemia, prolongation of bleeding time and prothrombin time (increased INR).

Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

Immune system disorders:

Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin (see section 4.4).

Angioedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis.

Nervous system disorders:

Reversible hyperactivity, aseptic meningitis and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Gastrointestinal disorders:

Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (refer to section 4.4).

Black ‘hairy’ tongue.

Superficial tooth discolouration has been reported especially with the suspension formulations. It can usually be removed by brushing.

Hepatobiliary disorders:

Hepatitis, cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

Hepatic events may be severe and fatal occurring predominantly in males and elderly patients and may be associated with prolonged treatment. 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.

Skin and subcutaneous tissue disorders:

Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS).

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

Renal and urinary disorders:

Interstitial nephritis, crystalluria (refer to section 4.9).

Reporting of suspected adverse reactions:

Reporting suspected adverse events after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '6.04 Adverse Drug Reaction Reporting form', found online under SAHPRA publications, https://www.sahpra.org.za/Publications/index/8.

4.9 Overdose:

Gastrointestinal symptoms (nausea, vomiting and diarrhoea) and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically, with attention to the water/electrolyte imbalance. AUGMENTIN may be removed from the circulation by haemodialysis.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (refer to section 4.4).

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

A.20.1.2 Penicillins

Bactericidal action:

The amoxicillin component of the formulations exerts a bactericidal action against many strains of Gram-positive and Gram-negative organisms. The clavulanic acid component has very little bactericidal action. It does however, by inactivation of susceptible β-lactamases, protect amoxicillin from degradation by a large number of β-lactamase enzymes produced

by penicillin-resistant strains of organisms. Potassium clavulanate has been shown *in vitro* to be an irreversible inhibitor of beta-lactamases.

In vitro sensitivity does not necessarily imply in vivo efficacy.

Species for which acquired resistance may be a problem
Gram-negative aerobes: *Escherichia coli** *Klebsiella oxytoca* *Klebsiella pneumoniae** *Klebsiella spp.* *Proteus mirabilis* *Proteus vulgaris* *Proteus spp.* *Salmonella spp.* *Shigella spp.*
Gram-positive aerobes: *Corynebacterium spp.* *Enterococcus faecium*
Inherently resistant organisms
Gram-negative aerobes: *Acinetobacter spp.* *Citrobacter freundii* *Enterobacter spp.* *Hafnia alvei* *Legionella pneumophila* *Morganella morganii* *Providencia spp.* *Pseudomonas spp.* *Serratia spp.*

Stenotrophomas maltophilia *Yersinia enterolitica*
Others: *Chlamydia pneumoniae* *Chlamydia psittaci* *Chlamydia spp.* *Coxiella burnetti* *Mycoplasma spp.*

5.2 Pharmacokinetic properties:

The two components of AUGMENTIN, amoxicillin and clavulanic acid are fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of AUGMENTIN is optimized when taken at the start of a meal. Amoxicillin serum concentrations achieved with the AUGMENTIN combination are similar to those produced by the oral administration of equivalent doses of amoxicillin alone.

Amoxicillin and clavulanic acid diffuse readily into most body tissues and fluids with the exception of the brain and spinal fluid. Neither amoxicillin nor clavulanic acid is highly protein bound, clavulanic acid is found to be approximately 25 % bound to human serum and amoxicillin approximately 18 % bound.

The major route of elimination for amoxicillin is the kidneys, whereas for clavulanic acid it is by both renal and non-renal mechanisms. Approximately 60-70 % of amoxicillin and 40-65 % clavulanic acid is excreted unchanged in urine during the first 6 hours after administration.

Amoxicillin is also partly excreted in the urine as the inactive metabolite (penicilloic acid) in quantities equivalent to 10-25 % of the initial dose. Clavulanic acid is extensively metabolised in man and the metabolites are eliminated in urine and faeces and as CO_2 in expired air.

Co-administration of probenecid has little effect on the excretion of the clavulanic acid component of the formulation, but delays amoxicillin excretion.

Pharmacokinetic studies performed in children, comparing AUGMENTIN three times a day and twice daily formulations, indicate that the elimination pharmacokinetics seen in adults also apply to children with mature kidney function.

The mean AUC values for amoxicillin are essentially the same following twice-a-day dosing or three-times-a-day dosing, in adults. No differences between the b.i.d and t.i.d dosing regimens are seen when comparing the amoxicillin $T_{1/2,}$ or C_{max} after normalisation for the different doses of amoxicillin administered. Similarly, no differences are seen for the clavulanate $T_{1/2,}$ C_{max} or AUC values after appropriate dose normalisation.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Excipients: aspartame, colloidal anhydrous silica, hydroxypropyl methylcellulose, silicone dioxide, succinic acid, xanthan gum, and raspberry, orange and golden syrup dry flavours.

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

The shelf life for the dry powder is 24 months. Bottles should be stored in a dry place, at or below 30 °C.

Once reconstituted the suspension should be used within 7 days and should be stored in a refrigerator (2 – 8 °C).

6.4 Special precautions for storage:

AUGMENTIN preparations should be stored in a cool, dry place at or below 30 °C.

AUGMENTIN suspensions, once reconstituted, should be kept in a refrigerator (2 °C to 8 °C) and used within 7 days. Do not freeze.

6.5 Nature and contents of container:

190/200 mL clear, colourless glass bottle containing an off-white powder for reconstitution to 140 mL suspension with a pilfer proof or child resistant closure.

147 mL clear, colourless glass bottle containing an off-white powder for reconstitution to 70 mL suspension

107 mL clear, colourless glass bottle containing an off-white powder for reconstitution to 35 mL suspension with a pilfer proof or child resistant closure.

6.6 Special precautions for disposal and other handling:

For reconstitution to 140 mL, first shake bottle to loosen powder, add 124 mL water, invert bottle and shake well until all the powder is dispersed. When first reconstituted allow to stand for 5 min to ensure full dispersion.

For reconstitution to 70 mL, first shake bottle to loosen powder, add 62 mL water, invert bottle and shake well until all the powder is dispersed.

For reconstitution to 35 mL, first shake bottle to loosen powder, add 31 mL water, invert bottle and shake well until all the powder is dispersed.

When first reconstituted allow to stand for 5 min to ensure full dispersion. The reconstituted suspension will be white to tan in colour.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

No 1 Bridgeway Road, Bridgeways Precinct

Century City

Cape Town

7441

8. REGISTRATION NUMBERS:

36/20.1.2/0367

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

02 July 2004

10. DATE OF REVISION OF THE TEXT:

09 May 2024

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Patient Information Leaflet

AUGMENTIN BD SF

Scheduling status: S4

AUGMENTIN BD SF Powder for suspension forte

Amoxicillin 400,0 mg/Clavulanic acid 57,0 mg

Sugar-free

Contains sweetener – each 5 mL contains 12,5 mg aspartame

Read all of this leaflet carefully before you or your child starts taking AUGMENTIN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AUGMENTIN has been prescribed for your child only and should not be shared with other people. It may harm them, even if their symptoms are the same.

What is in this leaflet:

1. What AUGMENTIN is and what it is used for
2. What you need to know before you take AUGMENTIN
3. How to take AUGMENTIN
4. Possible side effects
5. How to store AUGMENTIN
6. Contents of the pack and other information.

1. What AUGMENTIN is and what it is used for:

AUGMENTIN is an antibiotic which contains two active ingredients a penicillin called amoxicillin and clavulanic acid.

AUGMENTIN is used to treat children with infections caused by bacteria.

2. What you need to know before your child can take AUGMENTIN:

Your child should not receive AUGMENTIN if:

- he/she is allergic to amoxicillin or beta-lactam antibiotics (such as penicillins and cephalosporins) or any of the other ingredients of AUGMENTIN. If he/she have had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before you give AUGMENTIN
- he/she has ever had jaundice (yellowing of the skin and/or eyes) or liver disease while taking AUGMENTIN.

The safety of AUGMENTIN in children below 2 years of age has not been established.

Warnings and precautions:

Take special care with AUGMENTIN if:

- your child develops a skin rash while taking AUGMENTIN. Do not give any more suspension and tell your doctor at once
- your child has glandular fever (mononucleosis) and he/she is prescribed AUGMENTIN. Please tell the doctor before you give the medicine
- your child has liver or kidney problems. The dosage may need to be reduced or he/she may need to be given a different medicine
- your child suffers from a condition called phenylketonuria (PKU). This is because AUGMENTIN contains aspartame
- your child is not passing urine regularly and not able to drink water.

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. See POSSIBLE SIDE EFFECTS.

Other medicines and AUGMENTIN:

Always tell your healthcare professional if your child is taking any other medicine. (This includes complementary or traditional medicines).

It is particularly important that the doctor knows if your child is taking the following medicines:

- allopurinol
- probenecid
- anti-coagulants (used to prevent blood clots) such as warfarin
- mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).

AUGMENTIN with food or drink:

It is better to give your child AUGMENTIN at the same time as a meal, but AUGMENTIN still works if it is taken without food. Remember to give your child plenty of fluids such as water or non-alcoholic drinks.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine or giving to your child.

Driving and using machines:

AUGMENTIN has no effect on the ability to drive or operate machinery.

AUGMENTIN suspension contains aspartame, which is a source of phenylalanine. This is important if your child has a condition called phenylketonuria (PKU) and you must tell your doctor if they have this condition.

3. How to take AUGMENTIN:

Do not share medicines prescribed for your child with any other person.

Always take AUGMENTIN exactly as your doctor or pharmacist has told you.

The doctor will decide how much you need to give each day and how many days you should give it for.

If there is anything you do not understand please ask your doctor or pharmacist.

It is better to give AUGMENTIN at the start of, or just before, a meal but AUGMENTIN still works if it is given without food.

Make sure the whole dose is swallowed every time.

Once you have started giving AUGMENTIN:

Keep giving the medicine until the complete course has been finished. Do not stop when your child feels better.

If your child has taken more AUGMENTIN than they should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Give plenty of water to drink and contact a doctor. Show the doctor the pack of AUGMENTIN**.**

If you forget to take a dose of AUGMENTIN:

Give it as soon as you remember, then carry on as before**.**

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects:

AUGMENTIN can cause side effects.

Not all side effects reported for AUGMENTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If your child has any of the following symptoms after taking AUGMENTIN, STOP giving it and tell your doctor immediately, or take them to the accident and emergency department of your nearest hospital:

- sudden wheeziness, shortness of breath, or chest tightness
- swelling of the face, lips, tongue, or other parts of the body
- suddenly feeling faint, especially upon standing up
- convulsions (fits or seizures)
- yellowing of the skin and/or eyes, or dark coloured urine. These symptoms may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may not occur until several weeks after the end of treatment and can be severe
- blood in the urine which may be associated with a rash, fever, joint pain, or a reduction in passing water (urination)
- severe diarrhoea, which may be bloody, or contain mucus, and which may be accompanied by stomach cramps

- a rash with blisters that may cause the skin to peel, flake, or bleed.
- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale, and yellowing of the skin and/or eyes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AUGMENTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, severe chills, sore throat, or mouth ulcers. Unusual joint pains especially if accompanied by a rash
- the tongue may change colour to yellow, brown, or black, and it may have a hairy appearance
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- bleeding, or bruising, more easily than usual
- a rash where the spots (usually 0,5 cm to 2 cm in size) have a pink/red ring around the edge and a darker centre.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- mild rash, itching or hives (itchy lumps)
- indigestion
- headache
- dizziness
- diarrhoea (loose, or watery bowel movements)
- nausea (feeling sick)

- vomiting (being sick)
- thrush (a fungal infection). In babies this can look like a severe nappy rash. Older children may experience itching and burning around the genital area (private parts) with the presence of a thick, white discharge. Babies and children can also develop thrush in their mouth. This appears as painful white patches on the inside of their mouth and on their tongue.

Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving AUGMENTIN at the beginning of a meal.

Children's teeth can become discoloured while using AUGMENTIN. This is less likely to happen if they clean their teeth thoroughly and any discolouration can usually be removed by brushing. If the discolouration does not disappear, ask your doctor or dentist for advice.

Not all side effects reported for AUGMENTIN are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AUGMENTIN.

5. How to store AUGMENTIN:

Store all medicines out of reach of children**.**

Do not use after the expiry date stated on the label / carton / bottle.

Store in a dry place at or below 30°C in the original packaging. Keep tightly close.

Once made up, the suspension should be stored in a refrigerator (2°C to 8°C). Do not freeze it. Use the suspension within 7 days**.** Return all unused medicine to your pharmacist. Dispose of any unused suspension 7 days after first making up. Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

AUGMENTIN contains:

The active substances 400,0 mg amoxicillin and 57,0 mg clavulanic acid are present in 5 mL of suspension.

The other ingredients are aspartame, colloidal anhydrous silica, hydroxypropyl methylcellulose, silicone dioxide, succinic acid, xanthan gum, and raspberry, orange and golden syrup dry flavours.

What AUGMENTIN looks like and contents of the pack:

Off-white powder for reconstitution to an off-white suspension with an orange/raspberry flavour

Contents of the pack:

190/200 mL clear, colourless glass bottle containing an off-white powder for reconstitution to 140 mL suspension with a pilfer proof or child resistant closure.

147 mL clear colourless glass bottle containing an off-white powder for reconstitution to 70 mL suspension with a pilfer proof or child resistant closure.

107 mL clear colourless glass bottle containing an off-white powder for reconstitution to 35 mL suspension with a pilfer proof or child resistant closure.

When first reconstituted allow to stand for 5 min to ensure full dispersion. The reconstituted suspension will be white to tan in colour.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

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Century City

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7441

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