AUGMENTIN SUSPENSION RANGE

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

AUGMENTIN S Powder for Suspension

AUGMENTIN SF Powder for Suspension Forte

AUGMENTIN BD S Powder for Suspension

AUGMENTIN BD SF Powder for Suspension Forte

COMPOSITION:

AUGMENTIN S:

Powder for suspension, when reconstituted according to instructions each 5 ml contains amoxicillin trihydrate BP equivalent to 125 mg amoxicillin and potassium clavulanate equivalent to 31,25 mg clavulanic acid.

Sugar-free. Contains sweetener (aspartame 12,5 mg/5 ml).

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

AUGMENTIN SF:

Powder for suspension forte, when reconstituted according to instructions each 5 ml contains amoxicillin trihydrate BP equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62,5 mg clavulanic acid.

Sugar-free. Contains sweetener (aspartame 12,5 mg/5 ml).

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

AUGMENTIN BD S:

Powder for suspension, when reconstituted according to instructions each 5 ml contains amoxicillin trihydrate BP equivalent to 200 mg amoxicillin and potassium clavulanate equivalent to 28,5 mg clavulanic acid.

Sugar-free. Contains sweetener (aspartame 12,5 mg/5 ml).

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

AUGMENTIN BD SF:

Powder for suspension forte, when reconstituted according to instructions each 5 ml contains amoxicillin trihydrate BP equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57,0 mg clavulanic acid.

Sugar-free. Contains sweetener (aspartame 12,5 mg/5 ml).

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

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

Bacteriology:

(i) Spectrum - AUGMENTIN is the group name for formulations containing 2, 4 and 7 parts of a broad-spectrum penicillin, amoxicillin and 1 part of potassium clavulanate. Potassium clavulanate has been shown *in vitro* to be an irreversible inhibitor of beta-lactamases produced by: *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Haemophilus influenzae, Neisseria gonorrhoeae* and *Bacteroides fragilis.* Potassium clavulanate does not inactivate the chromosomally mediated (Sykes Type 1 Cephalosporinase) β-lactamases produced by

Acinetobacter species, *Citrobacter* species, *Enterobacter*, indole positive *Proteus, Providencia* species and *Serratia marcescens*. *In vitro* the formulation showed synergism against amoxicillin-resistant organisms, with no evidence of antagonism and the activity was not reduced in the presence of serum. (*In vitro* activity does not necessarily imply *in vivo* efficacy).

(ii) 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.

PHARMACOKINETICS:

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 optimised 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 regimes 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.

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**.**
- Lower respiratory tract infections, such as acute exacerbations of chronic bronchitis (caused by amoxicillin-resistant β-lactamase producing *Escherichia coli*, *Haemophilus influenzae* and *Haemophilus parainfluenzae*), bronchopneumonia.
- Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis.
- Skin and soft tissue infections.

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.

CONTRA-INDICATIONS:

In patients with a history of hypersensitivity to β-lactams e.g. penicillins and cephalosporins.

AUGMENTIN is contra-indicated in patients with a previous history of AUGMENTIN-associated jaundice/hepatic dysfunction.

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

WARNINGS AND SPECIAL PRECAUTIONS:

Serious and occasionally fatal hypersensitivity (anaphylactoid) 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 therapy instituted. Serious anaphylactoid reactions require emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation may also be required.

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 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 DOSAGE AND DIRECTIONS FOR USE.)

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

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.

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.

INTERACTIONS:

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 (Antabuse) like reaction in some patients. Therefore, the ingestion of alcohol should be avoided during and for several days after treatment with AUGMENTIN.

AUGMENTIN may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

PREGNANCY AND LACTATION:

Safety in pregnancy has not been established. There is limited information on the use of AUGMENTIN in pregnancy and its use should be avoided in pregnancy, unless considered essential by the physician**.**

Use in lactation:

AUGMENTIN may be administered during the period of lactation. Amoxicillin is excreted in breast milk. Trace quantities of clavulanate can be detected in breast milk. With the exception of the risk of sensitisation associated with this excretion, there are no known detrimental effects for the breastfed infant.

DOSAGE AND DIRECTIONS FOR USE:

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.

AUGMENTIN S: For reconstitution to 100 ml, add 92 ml water, invert bottle and shake well until all the powder is dispersed.

AUGMENTIN SF: For reconstitution to 100 ml, add 90 ml water, invert bottle and shake well until all the powder is dispersed.

AUGMENTIN BD S: For reconstitution to 70 ml, first shake bottle to loosen powder, add 64 ml water, invert bottle and shake well until all the powder is dispersed.

AUGMENTIN BD SF: 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.

Dosages:

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 in children is 25-50 mg/kg/day of the 4 parts amoxicillin, 1 part clavulanic acid preparations (which corresponds to a daily dosage of the equivalent of 20-40 mg/kg of amoxicillin and 5-10 mg/kg of clavulanic acid) to be taken in divided doses every eight hours, at the start of a meal.

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.

	4 : 1 Formulation	7 : 1 Formulation
Directions for use	In divided doses, three times per day (every 8 hours), at the start of a meal	In divided doses, twice daily (every 12 hours), at the start of a meal
Lower dose (mg/kg/day)	20/5-40/10	25/3,6-45/6,4
Higher dose (mg/kg/day)	40/10-60/15	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 S 13-21 kg (2-6 years)	5-10 ml [1)] 8 hourly	5-10 ml [1)] 8 hourly	5-10 ml [1)] 8 hourly	5-10 ml [1)] 8 hourly
AUGMENTIN SF 22-40 kg (7-12 years)	5 ml [1)] 8 hourly	5 ml [1)] 8 hourly	5 ml [1)] 8 hourly	5 ml [1)] 8 hourly
AUGMENTIN BD S 13-21 kg (2-6 years)	2,5-5 ml [3)] 12 hourly	2,5-5 ml [3)] 12 hourly	2,5-5 ml [3)] 12 hourly	2,5-5 ml [3)] 12 hourly
AUGMENTIN BD SF 22-40 kg (7-12 years)	5-10 ml [4)] 12 hourly	5-10 ml [4)] 12 hourly	5-10 ml [4)] 12 hourly	5-10 ml [4)] 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 S 13-21 kg (2-6 years)	5-10 ml [2] 8 hourly	5-10 ml [1] 8 hourly	5-10 ml [1] 8 hourly	5-10 ml [1] 8 hourly
AUGMENTIN SF 22-40 kg (7-12 years)	5-10 ml [2] 8 hourly	5-10 ml [1] 8 hourly	5-10 ml [1] 8 hourly	5-10 ml [1] 8 hourly
AUGMENTIN BD S 13-21 kg (2-6 years)	2,5-5 ml [3] 12 hourly	2,5-5 ml [3] 12 hourly	2,5-5 ml [3] 12 hourly	2,5-5 ml [3] 12 hourly
AUGMENTIN BD SF 22-40 kg (7-12 years)	5-10 ml [4] 12 hourly	5-10 ml [4] 12 hourly	5-10 ml [4] 12 hourly	5-10 ml [4] 12 hourly

1) To correspond to a dosage of 25-50 mg/kg/day

2) To correspond to a dosage of 50 mg/kg/day

3) To correspond to a dosage of 28,6 mg/kg/day

4) 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. The 4 : 1 suspensions are therefore recommended.

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. Only the 4 : 1 suspensions should be used in renal impairment.

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.

SIDE 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.

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

very common ≥1/10

common ≥1/100 and <1/10

uncommon ≥1/1 000 and <1/100

rare ≥1/10 000 and <1/1 000

very rare <1/10 000.

Infections and infestations:

Common: Mucocutaneous candidiasis (including vaginitis).

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 (see WARNINGS AND SPECIAL PRECAUTIONS).

Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

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 in those receiving high doses.

Gastrointestinal disorders:

Common: Diarrhoea, nausea, vomiting.

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

Uncommon: Indigestion.

Very rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). Superficial tooth discolouration has been reported which can usually be removed by brushing.

Abdominal pain, gastritis, stomatitis, glossitis, black “hairy” tongue, abnormal taste, tiredness and hot flushes have been reported.

Hepatobiliary disorders:

Uncommon: A moderate rise in AST and/or ALT has been noted in patients treated with β-lactam class antibiotics, but the significance of these findings is unknown.

Very rare: Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

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

Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. **Hepatic events may be severe and in extremely rare circumstances deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.**

Skin and subcutaneous tissue disorders:

Uncommon: Skin rash, pruritus, urticaria.

Rare: Erythema multiforme.

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

If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued. Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin (see WARNINGS AND SPECIAL PRECAUTIONS).

Renal and urinary disorders:

Very rare: Interstitial nephritis, crystalluria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Cases of overdosage with AUGMENTIN are usually asymptomatic. If encountered, 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.

IDENTIFICATION:

AUGMENTIN S**:** Off-white powder for reconstitution to a white to off-white suspension.

AUGMENTIN SF: Off-white powder for reconstitution to a white to off-white suspension.

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

AUGMENTIN BD SF**:** Off-white powder for reconstitution to an off-white suspension with an orange/raspberry flavour.

PRESENTATION:

AUGMENTIN S: Clear bottles containing off-white powder for reconstitution to suspension.

AUGMENTIN SF**:** Clear bottles containing off-white powder for reconstitution to suspension.

AUGMENTIN BD S**:** 147 ml Clear colourless glass bottle containing an off-white powder for reconstitution to 70 ml suspension.

AUGMENTIN BD SF**:** 147 ml Clear colourless glass bottle containing an off-white powder for reconstitution to 70 ml suspension, or 107 ml clear colourless glass bottle containing an off-white powder for reconstitution to 35 ml suspension.

STORAGE INSTRUCTIONS:

AUGMENTIN preparations should be stored in a cool, dry place below 25 °C.

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

AUGMENTIN S:	U/20.1.2/49
AUGMENTIN SF:	U/20.1.2/50
AUGMENTIN BD S:	36/20.1.2/0366
AUGMENTIN BD SF:	36/20.1.2/0367

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date of registration:

AUGMENTIN S: 08 September 1987

AUGMENTIN SF: 08 September 1987

AUGMENTIN BD: 02 July 2004

AUGMENTIN BD SF: 02 July 2004

Date compliant with Regulation 11:

12 September 2017

MDS-006

MANUFACTURER:

SmithKline Beecham Pharmaceuticals

Clarendon Road, Worthing, West Sussex, United Kingdom

Botswana:

Augmentin S - Reg No B9325220 S2

Augmentin SF - Reg No B9325225 S2

Augmentin BD S - Reg No BOT0701008 S2

Augmentin BD SF - Reg No BOT1502714 S2

Malawi:

Augmentin S – Reg No PMPB/PL 270/15 POM

Augmentin SF – Reg No PMPB/PL 270/85 POM

Augmentin BD S - Reg No PMPB/PL 270/84 POM

Augmentin BD SF - Reg No PMPB/PL 270/183 POM

Namibia:

Augmentin S - Reg No 90/20.1.2/001581 NS2

Augmentin SF - Reg No 90/20.1.2/001582 NS2

Augmentin BD S - Reg No 04/20.1.2/1735 NS2

Augmentin BD SF - Reg No 04/20.1.2/1736 NS2

Zambia:

Augmentin S - Reg No 179/045 POM

Augmentin SF - Reg No 179/030 POM

Augmentin BD S - Reg No 179/009 POM

Augmentin BD SF - Reg No 179/046 POM

Zimbabwe:

Augmentin BD S - Reg No 2014/7.1.2/4932 PP

Augmentin BD SF - Reg No 2014/7.1.2/4933 PP

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM EN DOSEERVORM:

AUGMENTIN S Poeier vir Suspensie

AUGMENTIN SF Poeier vir Suspensie Forte

AUGMENTIN BD S Poeier vir Suspensie

AUGMENTIN BD SF Poeier vir Suspensie Forte

SAMESTELLING:

AUGMENTIN S:

Poeier vir suspensie, wanneer hersaamgestel volgens instruksies bevat elke 5 ml, amoksisillientrihidraat BP ekwivalent aan 125 mg amoksisillien en kaliumklavulanaat ekwivalent aan 31,25 mg klavulaansuur.

Suikervry. Bevat versoeter (aspartaam 12,5 mg/ml).

Bestanddele: aspartaam, kolloïdale anhidriese silika, hidroksipropielmetielsellulose, silikoondioksied, barnsteensuur, xantaangom, en framboos, lemoen en goue stroop droë geurmiddels.

AUGMENTIN SF:

Poeier vir suspensie forte, wanneer hersaamgestel volgens instruksies bevat elke 5 ml, amoksisillientrihidraat BP ekwivalent aan 250 mg amoksisillien en kaliumklavulanaat ekwivalent aan 62,5 mg klavulaansuur.

Suikervry. Bevat versoeter (aspartaam 12,5 mg/ml).

Bestanddele: aspartaam, kolloïdale anhidriese silika, hidroksipropielmetielsellulose, silikoondioksied, barnsteensuur, xantaangom, en framboos, lemoen en goue stroop droë geurmiddels.

AUGMENTIN BD S:

Poeier vir suspensie, wanneer hersaamgestel volgens instruksies bevat elke 5 ml, amoksisillientrihidraat BP ekwivalent aan 200 mg amoksisillien en kaliumklavulanaat ekwivalent aan 28,5 mg klavulaansuur.

Suikervry. Bevat versoeter (aspartaam 12,5 mg/ml).

Bestanddele: aspartaam, kolloïdale anhidriese silika, hidroksipropielmetielsellulose, silikoondioksied, barnsteensuur, xantaangom, en framboos, lemoen en goue stroop droë geurmiddels.

AUGMENTIN BD SF:

Poeier vir suspensie forte, wanneer hersaamgestel volgens instruksies bevat elke 5 ml, amoksisillientrihidraat BP ekwivalent aan 400 mg amoksisillien en kaliumklavulanaat ekwivalent aan 57,0 mg klavulaansuur.

Suikervry. Bevat versoeter (aspartaam 12,5 mg/ml).

Bestanddele: aspartaam, kolloïdale anhidriese silika, hidroksipropielmetielsellulose, silikoondioksied, barnsteensuur, xantaangom, en framboos, lemoen en goue stroop droë geurmiddels.

FARMAKOLOGIESE KLASSIFIKASIE:

A 20.1.2 Penisilliene

FARMAKOLOGIESE WERKING:

Bakteriologie:

(i) Spektrum - AUGMENTIN is die groepnaam vir formulerings wat 2, 4 en 7 dele van ’n breë-spektrum penisillien, amoksisillien, en 1 deel kaliumklavulanaat bevat. Daar kon aangedui word dat kaliumklavulanaat *in vitro* ’n onomkeerbare inhibeerder van beta-laktamases is wat geproduseer word deur: *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Proteus vulgaris*, *Haemophilus influenzae*, *Neisseria gonorrhoeae* en *Bacteroides fragilis*. Kaliumklavulanaat inaktiveer nie die chromosoom-bemiddelde (Sykes Tipe 1 Sefalosporinase) β-laktamases wat deur *Acinetobacter* spesies, *Citrobacter* spesies,

Enterobacter, indool-positiewe *Proteus*, *Providencia* spesies en *Serratia marcescens* geproduseer word nie. *In vitro* het die formulering sinergisme teen amoksisillienweerstandige organismes getoon, sonder tekens van antagonisme en die aktiwiteit was ook nie in die teenwoordigheid van serum verlaag nie. (*In vitro* aktiwiteit beteken nie noodwendig *in vivo* doeltreffendheid nie).

(ii) Bakteriedodende werking - Die amoksisillienkomponent van die formulerings oefen 'n bakteriedodende werking teen baie stamme van Gram-positiewe en Gram-negatiewe organismes uit. Die klavulaansuurkomponent besit baie min bakteriedodende werking. Dit beskerm egter amoksillien teen degradasie deur 'n groot aantal β-laktamase ensieme wat deur penisillienweerstandige organismestamme geproduseer word, deur inaktivering van vatbare β-laktamases.

FARMAKOKINETIKA:

Die twee komponente van AUGMENTIN, amoksisillien en klavulaansuur, is volledig gedissosieer in waterig oplossing teen fisiologiese pH. Albei komponente word vinnig en goed deur die orale roete van toediening geabsorbeer. Optimum absorpsie van AUGMENTIN vind plaas wanneer dit aan die begin van 'n maaltyd geneem word. Serumkonsentrasies van amoksisillien wat met die AUGMENTIN-kombinasie bereik word, is soortgelyk aan dié wat verkry word deur orale toediening van ekwivalente dosisse van amoksisillien op sy eie.

Amoksisillien en klavulaansuur diffundeer maklik in die meeste liggaamsweefsels en vloeistowwe met die uitsondering van die brein en spinale vloeistof. Nóg amoksisillien, nóg klavulaansuur is hoogs proteïengebonde; daar word gevind dat ongeveer 25 % van klavulaansuur en ongeveer 18 % van amoksisillien aan menslike serum gebind is.

Die hoofroete van amoksisillien uitskeiding is die niere, terwyl vir klavulaansuur beide renale en nie-renale meganismes van toepassing is. Ongeveer 60-70 % van amoksisillien, en 40-65 % van klavulaansuur, word gedurende die eerste 6 uur na toediening onveranderd in die uriene uitgeskei.

Amoksisillien word ook gedeeltelik in die uriene as die onaktiewe metaboliet (penisilloïese suur) in hoeveelhede ekwivalent aan 10-25 % van die aanvanklike dosis, uitgeskei. Klavulaansuur word in die mens ekstensief gemetaboliseer en die metaboliete word in uriene en faeces en as CO_2 in uitgeasemde lug geëlimineer.

Gelyktydige toediening van probenesied het min uitwerking op die uitskeiding van die klavulaansuurkomponent van die formulering, maar dit vertraag uitskeiding van amoksisillien.

Farmakokinetiese studies wat op kinders uitgevoer is, waar AUGMENTIN drie-keer-per-dag- en twee-keer-per-dag-formulerings vergelyk is, het aangedui dat die eliminasie farmakokinetika wat in volwassenes waargeneem word, ook op kinders met volgroeide nierfunksie van toepassing is.

Die gemiddelde AOK-waardes vir amoksisillien is in volwassenes essensieel dieselfde na twee-keer-per-dag-dosering of drie-keer-per-dag-dosering. Geen verskille tussen die b.i.d. en t.i.d. doseringsregimens word waargeneem, wanneer die amoksillien-$T_{1/2}$ of -C_{maks} na normalisering vir die verskillende dosisse amoksisillien wat toegedien is, vergelyk word nie. Op soortgelyke wyse word geen verskille vir die klavulanaat-$T_{1/2}$ of -C_{maks} of AOK-waardes na toepaslike dosisnormalisering, waargeneem nie.

INDIKASIES:

AUGMENTIN-formulerings word aangedui vir die behandeling van infeksies wat deur amoksisillienweerstandige, β-laktamase-produserende organismes veroorsaak word, wat vir klavulaansuur sensitief is:

- Boonste lugweginfeksies, soos sinusitis, otitis media, herhaalde tonsillitis.
- Onderste lugweginfeksies, soos akute verergering van chroniese brongitis (veroorsaak deur amoksisillienweerstandige β-laktamase-produserende *Escherichia coli*, *Haemophilus influenzae* en *Haemophilus parainfluenzae*), brongopneumonie.
- Genito-urienweginfeksies, soos sistitis, uretritis, piëlonefritis.
- Vel- en sagteweefselinfeksies.

AUGMENTIN-formulerings sal ook teen die toepaslike dosering van amoksisillien doeltreffend wees in die behandeling van infeksies wat deur amoksisilliensensitiewe organismes veroorsaak word, aangesien die klavulaansuurkomponent nie tot die terapeutiese uitwerking bydra nie.

KONTRA-INDIKASIES:

In pasiënte met 'n geskiedenis van hipersensitiwiteit teenoor β-laktaammiddels, bv. penisilliene en sefalosporiene.

AUGMENTIN is teenaangedui in pasiënte met 'n vorige geskiedenis van AUGMENTIN-gekoppelde geelsug/hepatiese disfunksie.

Veiligheid in kinders jonger as 2 maande is nie vasgestel nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Ernstige en soms noodlottige hipersensitiwiteits-(anafilaktoïede) reaksies is by pasiënte op penisillienterapie aangemeld. Alhoewel anafilakse meer dikwels na parenterale terapie voorkom, het dit al in pasiënte op orale penisilliene voorgekom. Hierdie reaksies sal meer geneig wees om in individue met 'n geskiedenis van penisillienhipersensitiwiteit en/of 'n geskiedenis van sensitiwiteit teenoor veelvoudige allergene, voor te kom. Berig is ontvang van individue met 'n geskiedenis van penisillienhipersensitiwiteit, wat ernstige reaksies ondervind het toe hulle met sefalosporiene behandel is. Voordat AUGMENTIN-terapie ingestel word, moet versigtig ondersoek ingestel word oor vorige hipersensitiwiteitsreaksies teen penisilliene, sefalosporiene of ander allergene. Indien 'n allergiese reaksie voorkom, moet AUGMENTIN gestaak, en die toepaslike terapie begin word. Ernstige anafilaktoïede reaksies benodig noodbehandeling met adrenalien. Suurstof, intraveneuse steroïede en beheer van lugweë, insluitend intubasie, mag ook nodig wees.

Omdat AUGMENTIN amoksisillien, 'n aminopenisillien bevat, is dit nie die behandeling van keuse in pasiënte met seer keel of faringitis nie as gevolg van die moontlikheid dat die

onderliggende oorsaak infektiewe mononukleose mag wees, in die teenwoordigheid waarvan 'n hoë voorkoms van veluitslag voorkom indien amoksisillien gebruik word. AUGMENTIN behoort vermy te word indien infektiewe mononukleose vermoed word.

Veranderings in lewerfunksietoetse is waargeneem in sommige pasiënte wat AUGMENTIN ontvang het. Lewerfunksie behoort op gereelde tussenposes gemoniteer te word. Verbygaande hepatitis en cholestatiese geelsug is aangemeld. AUGMENTIN behoort met omsigtigheid in pasiënte met tekens van lewerdisfunksie gebruik te word.

In pasiënte met nierinkorting, behoort doserings volgens die graad van inkorting aangepas te word. (Sien DOSIS EN GEBRUIKSAANWYSINGS).

Langdurige gebruik mag soms oormatige groei van nie-vatbare organismes veroorsaak. Die moontlikheid van superinfeksies met mikotiese of bakteriële patogene moet tydens terapie in gedagte gehou word. Indien superinfeksies voorkom (wat gewoonlik *Aerobacter*, *Pseudomonas* of *Candida* betref), moet AUGMENTIN gestaak en/of toepaslike terapie ingestel word.

Die gebruik van hierdie antibiotika mag lei tot die seleksie van weerstandige organismestamme en sensitiwiteitstoetse moet dus wanneer moontlik, uitgevoer word om die toepaslikheid van terapie te demonstreer.

Periodieke bepaling van orgaansisteemfunksies, insluitend nier-, lewer- en hematopoïetiese funksie, is raadsaam tydens langdurige terapie.

AUGMENTIN behoort met omsigtigheid in pasiënte met limfatiese leukemie gebruik te word omdat hulle besonder vatbaar is vir amoksisillien-geïnduseerde veluitslae.

AUGMENTIN-suspensies bevat aspartaam en moet met omsigtigheid in pasiënte met fenielketonurie gebruik word.

INTERAKSIES:

Probenesied verminder die nierbuisuitskeiding van amoksisillien, maar dit beïnvloed nie uitskeiding van klavulaansuur nie. Gelyktydige gebruik saam met AUGMENTIN mag verhoogde bloedvlakke van amoksisillien veroorsaak, wat lank aanhou, maar nie van klavulaansuur nie.

Die gelyktydige toediening van allopurinol en ampisillien kan moontlik die voorkoms van veluitslae in pasiënte wat albei middels ontvang in vergelyking met pasiënte wat net ampisillien ontvang, aansienlik verhoog. Dit is nie bekend of hierdie vermeerdering van ampisillienveluitslae die gevolg is van allopurinol of die hiperurisemie wat in hierdie pasiënte teenwoordig is nie. Daar bestaan geen data oor die gelyktydige inname van AUGMENTIN en allopurinol nie.

Geen inligting is oor die gelyktydige gebruik van AUGMENTIN en alkohol beskikbaar nie. Inname van alkohol tydens behandeling met sommige ander β-laktaam-antibiotika het egter ’n reaksie wat soortgelyk was aan dié wat deur disulfiram (Antabuse) veroorsaak word in sommige pasiënte veroorsaak. Inname van alkohol behoort dus tydens en vir ’n paar dae na behandeling met AUGMENTIN, vermy te word.

AUGMENTIN mag die doeltreffendheid van orale voorbehoedmiddels verminder en pasiënte moet dienooreenkomstige gewaarsku word.

SWANGERSKAP EN LAKTASIE:

Veiligheid in swangerskap is nie vasgestel nie. Slegs beperkte inligting is beskikbaar oor die gebruik van AUGMENTIN in swangerskap en die gebruik daarvan behoort dus tydens swangerskap vermy te word, tensy dit deur die geneesheer as essensieel beskou word.

Gebruik in laktasie:

AUGMENTIN mag gedurende die laktasieperiode toegedien word. Amoksisillien word in borsmelk uitgeskei. Spore van klavulanaat kan in borsmelk opgespoor word. Met die uitsondering van die risiko van sensitisering wat met hierdie uitskeiding gepaard gaan, is daar geen bekende nadelige uitwerkings vir die borsgevoede suigeling nie.

DOSIS EN GEBRUIKSAANWYSINGS:

AUGMENTIN suspensies moet onmiddellik voor 'n maaltyd geneem word.

Die duur van terapie behoort toepaslik vir die aanduiding te wees en behoort nie 14 dae sonder hersiening te oorskry nie.

AUGMENTIN S: Vir hersamestelling tot 100 ml, voeg 92 ml water by, keer die bottel om en skud goed totdat al die poeier gedispergeer is.

AUGMENTIN SF: Vir hersamestelling tot 100 ml, voeg 90 ml water by, keer die bottel om en skud goed totdat al die poeier gedispergeer is.

AUGMENTIN BD S: Vir hersamestelling tot 70 ml, skud eers die bottel om poeier los te maak, voeg 64 ml water by, keer die bottel om en skud goed totdat al die poeier gedispergeer is.

AUGMENTIN BD SF: Vir hersamestelling tot 70 ml, skud eers die bottel om poeier los te maak, voeg 62 ml water by, keer die bottel om en skud goed totdat al die poeier gedispergeer is.

Vir hersamestelling tot 35 ml, skud eers die bottel om poeier los te maak, voeg 31 ml water by, keer die bottel om en skud goed totdat al die poeier gedispergeer is.

Laat staan vir 5 minute na eerste hersamestelling om volledige dispersie te verseker.

Doserings:

Algemene Inligting:

Vir infeksies wat deur amoksisilliensensitiewe organismes veroorsaak word, is die dosering dié wat vir amoksisillien goedgekeur word aangesien die klavulaansuurkomponent nie tot die terapeutiese uitwerking bydra nie.

Dosering is van die ouderdom, gewig en nierfunksie van die pasiënt en die erns van die infeksie, afhanklik.

Kinders 2-12 jaar:

Die dosis AUGMENTIN in kinders is 25-50 mg/kg/dag van die 4 dele amoksisillien, 1 deel klavulaansuur voorbereidings (wat ooreenstem met ’n daaglikse dosering wat ekwivalent is aan 20-40 mg/kg amoksisillien en 5-10 mg/kg klavulaansuur), wat in verdeelde dosisse elke agt uur aan die begin van ’n maaltyd geneem moet word.

Die dosis AUGMENTIN BD in kinders is 28,6-51,4 mg/kg/dag van die 7 dele amoksisillien, 1 deel klavulaansuur voorbereidings (wat ooreenstem met ’n daaglikse dosering wat ekwivalent is aan 25-45 mg/kg amoksisillien en 3,6-6,4 mg/kg klavulaansuur), wat in verdeelde dosisse elke twaalf uur aan die begin van ’n maaltyd geneem moet word.

	4 : 1 Formulering	7 : 1 Formulering
Gebruiksaanwysings	In verdeelde dosisse, drie keer per dag (elke 8 uur), aan die begin van ’n maaltyd	In verdeelde dosisse, twee keer per dag (elke 12 uur), aan die begin van ’n maaltyd
Laer dosis (mg/kg/dag)	20/5-40/10	25/3,6-45/6,4
Hoër dosis (mg/kg/dag)	40/10-60/15	45/6,4-70/10

Die laer dosis word vir infeksies soos byvoorbeeld van die vel en sagteweefsel en herhaalde tonsilitis, aanbeveel.

Die hoër dosis word aanbeveel vir infeksies soos otitis media, sinusitis, laer lugweginfeksies en urienweginfeksies.

Kinders wat 40 kg en meer weeg, behoort volgens volwasse aanbevelings gedoseer te word.

Doseringsriglyn:

AMOKSISILLIENSENSITIEWE ORGANISMES

PRODUK	**BOONSTE LUGWEG-INFEKSIES**	**ONDERSTE LUGWEG-INFEKSIES**	**URIENWEG-INFEKSIES**	**VEL- EN SAGTE-WEEFSEL-INFEKSIES**
AUGMENTIN S 13-21 kg (2-6 jaar)	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur
AUGMENTIN SF 22-40 kg (7-12 jaar)	5 ml [1)] Elke 8 uur	5 ml [1)] Elke 8 uur	5 ml [1)] Elke 8 uur	5 ml [1)] Elke 8 uur
AUGMENTIN BD S 13-21 kg (2-6 jaar)	2,5-5 ml [3)] Elke 12 uur	2,5 - 5 ml [3)] Elke 12 uur	2,5-5 ml [3)] Elke 12 uur	2,5-5 ml [3)] Elke 12 uur
AUGMENTIN BD SF 22-40 kg (7-12 jaar)	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur

AMOKSISILLIENWEERSTANDIGE ORGANISMES

PRODUK	**BOONSTE LUGWEG-INFEKSIES (otitis media)** ***H. influenzae*** ***H. parainfluenzae***	***ONDERSTE LUGWEG-INFEKSIES (brongitis)*** ***H. influenzae*** ***H. parainfluenzae***	***URIENWEG-INFEKSIES*** ***E. coli*** ***Klebsiella pneumoniae***	***VEL- EN SAGTE-WEEFSEL-INFEKSIES*** ***Staphylococcus aureus***
AUGMENTIN S 13-21 kg (2-6 jaar)	5-10 ml [2)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur

AUGMENTIN SF 22-40 kg (7-12 jaar)	5-10 ml [2)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur	5-10 ml [1)] Elke 8 uur
AUGMENTIN BD S 13-21 kg (2-6 jaar)	2,5-5 ml [3)] Elke 12 uur	2,5-5 ml [3)] Elke 12 uur	2,5-5 ml [3)] Elke 12 uur	2,5-5 ml [3)] Elke 12 uur
AUGMENTIN BD SF 22-40 kg (7-12 jaar)	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur	5-10 ml [4)] Elke 12 uur

1) Om ooreen te stem met 'n dosering van 25-50 mg/kg/dag

2) Om ooreen te stem met 'n dosering van 50 mg/kg/dag

3) Om ooreen te stem met 'n dosering van 28,6 mg/kg/dag

4) Om ooreen te stem met 'n dosering van 51,4 mg/kg/dag.

Kinders van 2 maande tot 2 jaar:

Kinders jonger as 2 jaar behoort volgens liggaamsgewig gedoseer te word.

Augmentin BD suspensies word nie vir kinders jonger as 2 maande aanbeveel nie, omdat die dosis weens die onvolwasse nierfunksie volgens die amoksisillieninhoud aangepas sal moet word. Met hoë amoksisillien/klavulanaat-verhoudings kan dit egter lei tot verminderde dosisse klavulanaat en sulke dosisse is nog nie in hierdie groep pasiënte bestudeer nie.

Die 4 : 1 suspensies word dus aanbeveel.

Ingekorte nierfunksie:

Beide amoksisillien en klavulaansuur word deur die niere uitgeskei en die serumhalfleeftyd van elkeen, maar veral van amoksisillien, verhoog in pasiënte met nierversaking. Dit mag dus nodig wees om die dosis te verlaag of die doseringsinterval te verleng. Dosisaanpassing word op die maksimum aanbevole vlak van amoksisillien gegrond. Die volgende skedule word voorgestel:

Ligte inkorting	Matige inkorting	Ernstige inkorting
Kreatienopruiming meer as 30 ml/minuut	Kreatienopruiming 10 tot 30 ml/minuut	Kreatienopruiming minder as 10 ml/minuut
Geen verandering in dosis nie.	15/3,75 mg/kg wat elke 12 uur gegee word.	15/3,75 mg/kg wat as 'n enkele daaglikse dosis gegee word.
	Maksimum amoksillien-dosis: 30 mg/kg/dag.	Maksimum amoksillien-dosis: 15 mg/kg/dag.

AUGMENTIN BD suspensies word NIE vir kinders met kreatienopruiming van minder as 30 ml/min aanbeveel NIE. Slegs die 4 : 1 suspensies behoort in nierinkorting gebruik te word.

Geen dosisaanbevelings kan vir vroeggeborenes gemaak word nie.

Hemodialise verminder serumkonsentrasies van beide amoksisillien en klavulaansuur en 'n addisionele dosis behoort aan die einde van dialise toegedien te word.

NEWE-EFFEKTE:

Data van groot kliniese studies is gebruik om die frekwensie van baie algemene tot seldsame ongewenste uitwerkings te bepaal. Die frekwensies wat aan alle ander ongewenste uitwerkings toegeken is (d.i. dié wat teen <1/10 000 voorkom), is hoofsaaklik bepaal deur nabemarkingdata te gebruik en te verwys na 'n aanmeldingskoers in plaas van ware frekwensie.

Die volgende konvensie is vir die klassifisering van frekwensie gebruik:

baie algemeen ≥1/10

algemeen ≥1/100 en <1/10

ongewoon ≥1/1 000 en <1/100

seldsaam ≥1/10 000 en <1/1 000

baie seldsaam <1/10 000.

Infeksies en besmettings:

Algemeen: Mukokutane kandidiase (insluitend vaginitis).

Siektes van die bloed- en limfatiese sisteem:

Seldsaam: Omkeerbare leukopenie (insluitend neutropenie) en trombositopenie.

Baie seldsaam: Omkeerbare agranulositose en hemolitiese anemie. Verlenging van bloeityd en protrombientyd (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

Toepaslike monitering moet onderneem word wanneer antikoagulante gelyktydig voorgeskryf word.

Siektes van die immuunsisteem:

Baie seldsaam: Angioneurotiese edeem, anafilakse, serumsiekte-soortgelyke sindroom, hipersensitiwiteit-vaskulitis.

Siektes van die senusisteem:

Ongewoon: Duiseligheid, hoofpyn.

Baie seldsaam: Omkeerbare hiperaktiwiteit en konvulsies. Konvulsies mag voorkom in pasiënte met ingekorte nierfunksie of by pasiënte wat hoë dosisse ontvang.

Gastroïntestinale siektes:

Algemeen: Diarree, naarheid, braking.

Naarheid word meer dikwels met hoër orale doserings geassosieer. Indien gastroïntestinale reaksies voorkom, kan dit verminder word deur AUGMENTIN aan die begin van ’n maaltyd te neem.

Ongewoon: Swak spysvertering.

Baie seldsaam: Antibiotika-geassosieerde kolitis (insluitend pseudomembraneuse kolitis en hemoragiese kolitis). Oppervlakkige verkleuring van die tande is aangemeld, wat gewoonlik verwyder kan word deur die tande te borsel.

Abdominale pyn, gastritis, stomatitis, glossitis, swart “harige” tong, abnormale smaak, moegheid en warm gloede is aangemeld.

Hepatobiliêre siektes:

Ongewoon: 'n Matige verhoging in AST en/of ALT is waargeneem in pasiënte wat met antibiotika van die β-laktaam-klas behandel is, maar die belangrikheid van hierdie bevindings is onbekend.

Baie seldsaam: Hepatitis en cholestatiese geelsug. Hierdie voorvalle is met ander penisilline en sefalosporiene waargeneem.

Hepatiese voorvalle is hoofsaaklik in mans en bejaarde pasiënte gerapporteer en mag verband hou met langdurige behandeling. Hierdie voorvalle is baie selde in kinders aangemeld.

Tekens en simptome kom gewoonlik voor tydens behandeling, of kort daarna, maar in sommige gevalle mag dit nie waargeneem word tot etlike weke na die einde van behandeling nie. Dit is gewoonlik omkeerbaar. **Hepatiese voorvalle mag ernstig wees en in uiters seldsame omstandighede is sterftes aangemeld. Dit het amper altyd in pasiënte met ernstige onderliggende siekte of wat gelyktydige medikasies geneem het, waar dit bekend is dat dit potensieel hepatiese uitwerkings kan veroorsaak, voorgekom.**

Siektes van die vel- en subkutane weefsel:

Ongewoon: Veluitslag, pruritus, urtikarie.

Seldsaam: Erythema multiforme.

Baie seldsaam: Stevens-Johnson-sindroom, toksiese epidermale nekrolise, bulleuse eksfoliatiewe dermatitis, akute veralgemeende eksanteemagtige pustulose (AGEP).

Indien enige hipersensitiwiteitsreaksies van die vel voorkom, behoort behandeling gestaak te word. Ernstige en soms noodlottige hipersensitiwiteits-(anafilaktiese) reaksies en angioneurotiese edeem kan met orale penisillien voorkom (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

Renale en urinêre siektes:

Baie seldsaam: Interstisiële nefritis, kristalurie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Gevalle van oordosering met AUGMENTIN is gewoonlik asimptomaties. Indien dit voorkom, mag gastroïntestinale simptome (naarheid, braking en diarree) en versteuring van die vloeistof- en elektrolietbalanse teenwoordig wees. Dit kan simptomaties behandel word terwyl aandag aan die water-/elektrolietwanbalans geskenk word. AUGMENTIN kan van die bloedsomloop deur hemodialise verwyder word.

IDENTIFIKASIE:

AUGMENTIN S: Naaswit poeier vir hersamestelling na ’n wit tot naaswit-suspensie.

AUGMENTIN SF: Naaswit poeier vir hersamestelling na ’n wit tot naaswit-suspensie.

AUGMENTIN BD S: Naaswit poeier vir hersamestelling na ’n naaswit suspensie met ’n lemoen-/framboosgeur.

AUGMENTIN BD SF: Naaswit poeier vir hersamestelling na ’n naaswit suspensie met ’n lemoen-/framboosgeur.

AANBIEDING:

AUGMENTIN S: Helder bottels wat ’n naaswit poeier vir hersamestelling na suspensie bevat.

AUGMENTIN SF: Helder bottels wat ’n naaswit poeier vir hersamestelling na suspensie bevat.

AUGMENTIN BD S: 147 ml Helder kleurlose glasbottel wat ’n naaswit poeier vir hersamestelling tot 70 ml suspensie bevat.

AUGMENTIN BD SF: 147 ml Helder kleurlose glasbottel wat ’n naaswit poeier vir hersamestelling tot 70 ml suspensie bevat of 107 ml helder kleurlose glasbottel wat ’n naaswit poeier vir hersamestelling tot 35 ml suspensie bevat.

BERGINGSAANWYSINGS:

AUGMENTIN-preparate moet in ’n koel, droë plek benede 25 °C bewaar word.

Na hersamestelling moet AUGMENTIN-suspensies in ’n yskas (2 °C tot 8 °C) bewaar, en binne 7 dae gebruik word. Moenie vries nie.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

AUGMENTIN S:	U/20.1.2/49
AUGMENTIN SF:	U/20.1.2/50
AUGMENTIN BD S:	36/20.1.2/0366
AUGMENTIN BD SF:	36/20.1.2/0367

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:

Datum van registrasie:

AUGMENTIN S: 08 September 1987

AUGMENTIN SF: 08 September 1987

AUGMENTIN BD: 02 Julie 2004

AUGMENTIN BD SF: 02 Julie 2004

Datum voldoen aan Regulasie 11:

12 September 2017