NEW ZEALAND DATA SHEET

1. PRODUCT NAME

AUGMENTIN 600 mg and 1.2 g powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

AUGMENTIN 600 mg: Each vial contains amoxicillin sodium equivalent to 500 mg of amoxicillin and potassium clavulanate equivalent to 100 mg of clavulanic acid.

AUGMENTIN 1.2 g: Each vial contains amoxicillin sodium equivalent to 1 g of amoxicillin and potassium clavulanate equivalent to 200 mg of clavulanic acid.

For the full list of excipients, see section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Powder for injection. For reconstitution as an intravenous (IV) injection or infusion.

Vials containing a sterile white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

AUGMENTIN is indicated for the short term treatment of common bacterial infections in adults and children such as:

Upper Respiratory Tract Infections (including ENT): e.g. tonsillitis, sinusitis, otitis media

Lower Respiratory Tract Infections: e.g. acute exacerbations of chronic bronchitis, lobar and broncho-pneumonia

Genito-urinary Tract Infections: e.g. cystitis, urethritis, pyelonephritis, female genital infections

Skin and Soft Tissue Infections

Bone and Joint Infections: e.g. osteomyelitis

Other Infections: e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis, septicaemia, peritonitis, post-surgical infections

AUGMENTIN is indicated for prophylaxis against infection which may be associated with major surgical procedures such as gastro-intestinal, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract surgery.

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

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

4.2 Dose and method of administration

Dose

Adults and Children 40 kg and over: Usually 1.2 g 8 hourly. In more serious infections, increase frequency to 6 hourly intervals.

Children 3 months - 12 years: Usually 30 mg/kg* AUGMENTIN 8 hourly. In more serious infections, increase frequency to 6 hourly intervals.

Children 0-3 months: 30 mg/kg* AUGMENTIN every 12 hours in infants < 4 kg and 30 mg/kg* AUGMENTIN every 8 hours in infants >4 kg

*Each 30 mg AUGMENTIN provides 5 mg clavulanic acid with 25 mg amoxicillin.

Dosage for surgical prophylaxis: Surgical prophylaxis with AUGMENTIN should aim to protect the patient for the period of risk of infection. Accordingly, procedures in adults lasting for less than 1 hour are successfully covered by 1.2 g AUGMENTIN Intravenous given at induction of anaesthesia. Longer operations require subsequent doses of 1.2 g AUGMENTIN IV (up to 4 doses in 24 hours), and this regime can be continued for several days if the procedure has significantly increased the risk of infection. Clear clinical signs of infection at operation will require a normal course of IV or oral AUGMENTIN therapy post-operatively.

Special populations

Elderly

No adjustment needed, dose as for adults. If there is evidence of renal impairment, dose should be adjusted as for renally impaired adults (see below).

Renal impairment

Adults: Dosing adjustments are based on the maximum recommended level of amoxicillin.

	Mild Impairment (creatinine clearance >30 mL/min)	Moderate Impairment (creatinine clearance 10-30 mL/min)	Severe Impairment (creatinine clearance <10 mL/min)
Intravenous	No change in dosage	1.2 g IV stat followed by 600 mg IV 12 hourly	1.2 g IV stat followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of AUGMENTIN. An additional

			600 mg IV dose may need to be supplemented at the end of dialysis

Each 1.2 g vial of AUGMENTIN contains 1.0 mmoL of potassium and 3.1 mmoL of sodium (approx.).

Children: Dosing adjustments are based on the maximum recommended level of amoxicillin.

	Mild Impairment (creatinine clearance >30 mL/min)	Moderate Impairment (creatinine clearance 10-30 mL/min)	Severe Impairment (creatinine clearance <10 mL/min)
Intravenous	No change in dosage	30 mg/kg 12 hourly	30 mg/kg every 24 hours Dialysis decreases serum concentrations of AUGMENTIN. An additional 15 mg/kg may need to be supplemented at the end of dialysis, then 30 mg/kg/day

Hepatic impairment

Dose with caution; monitor hepatic function at regular intervals for both adults and children.

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

Method of administration

AUGMENTIN may be administered either by intravenous injection or by intermittent infusion. It is not suitable for intramuscular administration.

IV injection: AUGMENTIN should be given by slow intravenous injection over a period of 3-4 minutes and within 20 minutes of reconstitution. It may be injected directly into the vein or via a drip tube.

IV infusion: Infuse AUGMENTIN over 30-40 minutes and complete within the times stated.

For instructions on reconstitution of the medicine before administration, see section 6.6 Special precautions for disposal and other handling.

4.3 Contraindications

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

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

4.4 Special warnings and precautions for use

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

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse 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, AUGMENTIN therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation may also be required.

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

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

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

In general AUGMENTIN 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.

AUGMENTIN should be used with caution in patients with evidence of hepatic dysfunction.

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.

In patients with renal impairment, dosage should be adjusted according to the degree of impairment (see section 4.2 Dose and method of administration).

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

The occurrence at treatment initiation of a feverish generalised erythema associated with pustule may be a symptom of acute generalised exanthemous pustulosis (AEGP). This reaction requires AUGMENTIN discontinuation and is a contraindication to subsequent administration of amoxicillin.

The presence of clavulanic acid in AUGMENTIN may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet.

In patients with reduced urine output crystalluria has been observed very rarely, predominantly with parenteral therapy. During 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 (see section 4.9 Overdose).

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with AUGMENTIN may result in increased and prolonged blood levels of amoxicillin, but not of 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 AUGMENTIN and allopurinol.

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

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

The presence of clavulanic acid in AUGMENTIN may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

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

<u>Pregnancy</u>

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parentally administered AUGMENTIN have shown no teratogenic effects. In a single study in women with preterm, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with AUGMENTIN may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Breast-feeding

AUGMENTIN may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breastfed infant.

Fertility

There are no data on the effects of amoxicillin sodium/potassium clavulanate on fertility in humans.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Tabulated list of adverse reactions

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 ≥1/1000 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: Aseptic meningitis, reversible hyperactivity and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Vascular disorders:

Rare: Thrombophlebitis at the site of injection

Gastrointestinal disorders following intravenous administration:

Common: Diarrhoea

Uncommon: Nausea, vomiting, indigestion

Very rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (see section 4.4 Special warnings and precautions for use) are less likely to occur after parenteral administration.

In all populations 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.

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.

(see section 4.4 Special warnings and precautions for use)

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), and drug reaction with eosinophilia and systemic symptoms (DRESS)

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

Renal and urinary disorders:

Very rare: Interstitial nephritis, crystalluria (see section 4.9 Overdose)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions 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 via: https://nzphvc.otago.ac.nz/reporting.

4.9 Overdose

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

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see section 4.4 Special warnings and precautions for use).

Amoxicillin has been reported to precipitate in bladder catheters after intravenous administration of large doses. A regular check of patency should be maintained.

AUGMENTIN can be removed from the circulation by haemodialysis.

A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250mg/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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors; ATC code: J01CR02.

Mechanism of Action

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

Amoxicillin is a semisynthetic antibiotic with a broad spectrum of antibacterial activity against many gram-positive and gram-negative micro-organisms. Amoxicillin is, however susceptible to degradation by beta-lactamases and therefore the spectrum

of activity of amoxicillin alone does not include organisms which produce these enzymes.

Clavulanic acid is a beta-lactam, structurally related to the penicillins, which possesses the ability to inactivate a wide range of beta-lactamase enzymes commonly found in micro-organisms resistant to penicillins and cephalosporins. In particular, it has good activity against the clinically important plasmid mediated beta-lactamases frequently responsible for transferred drug resistance. It is generally less effective against chromosomally-mediated type 1 beta-lactamases.

The presence of clavulanic acid in AUGMENTIN formulations protects amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibacterial spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other penicillins and cephalosporins. Thus AUGMENTIN possesses the distinctive properties of a broad spectrum antibiotic and a beta-lactamase inhibitor.

Pharmacodynamic Effects

In the list below, organisms are categorised according to their in vitro susceptibility to amoxicillin-clavulanate.

In vitro susceptibility of micro-organisms to amoxicillin-clavulanate Where clinical efficacy of amoxicillin-clavulanate has been demonstrated in clinical trials this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxicillin, it can be considered susceptible to amoxicillin-clavulanate.
Commonly susceptible species
Gram-positive aerobes:
Bacillius anthracis
Enterococcus faecalis
Gardnerella vaginalis
Listeria monocytogenes
Nocardia asteroides
*Streptococcus pneumoniae**†
*Streptococcus pyogenes**†
*Streptococcus agalactiae**†
Viridans group streptococcus†
Streptococcus spp. (other β-hemolytic)*†
Staphylococcus aureus (methicillin susceptible)*
Staphylococcus saprophyticus (methicillin susceptible)
Coagulase negative staphylococcus (methicillin susceptible)
Gram-negative aerobes:
Bordetella pertussis

*Haemophilus influenzae**
Haemophilus parainfluenzae
Helicobacter pylori
*Moraxella catarrhalis**
Neisseria gonorrhoeae
Pasteurella multocida
Vibrio cholerae
Other:
Borrelia burgdorferi
Leptospira ictterohaemorrhagiae
Treponema pallidum
Gram-positive anaerobes:
Clostridium spp.
Peptococcus niger
Peptostreptococcus magnus
Peptostreptococcus micros
Peptostreptococcus spp.
Gram-negative anaerobes:
Bacteroides fragilis
Bacteroides spp.
Capnocytophaga spp.
Eikenella corrodens
Fusobacterium nucleatum
Fusobacterium spp.
Porphyromonas spp.
Prevotella spp.

Species for which acquired resistance may be a problem
Gram-negative aerobes:
*Escherichia coli**
Klebsiella oxytoca
*Klebsiella pneumoniae**
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Proteus spp.
Salmonella spp.
Shigella spp.
Gram-positive aerobes:
Corynebacterium spp.
Enterococcus faecium
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

Absorption

The two components of AUGMENTIN, amoxicillin and clavulanic acid are fully dissociated in aqueous solution at physiological pH. The pharmacokinetic results for studies in which AUGMENTIN was administered to groups of healthy volunteers as either 500/100 (600 mg) or 1000/200 mg (1.2 g) given as a bolus intravenous injection are presented below.

	Mean Pharmacokinetic Parameters				
		Mean Peak Serum Conc	T ½ hours	AUC hours	Urinary recovery
Drug Administration		Mcg/mL		h.mg/L	0 – 6 hrs%
Amoxicillin	Amox dose				
AUGMENTIN 500/100 mg	500 mg	32.2	1.07	25.5	66.5
AUGMENTIN 1000/200 mg	1 g	105.4	0.9	76.3	77.4

	Mean Pharmacokinetic Parameters				
		Mean Peak Serum Conc	T ½ hours	AUC hours	Urinary recovery
Drug Administration		Mcg/mL		h.mg/L	0 – 6 hrs%
Clavulanic acid	CVA dose				
AUGMENTIN 500/100 mg	100 mg	10.5	1.12	9.2	46.0
AUGMENTIN 1000/200 mg	200 mg	28.5	0.9	27.9	63.8

Distribution

Following intravenous administration therapeutic concentrations of both amoxicillin and clavulanic acid may be detected in the tissues and interstitial fluid. Therapeutic concentrations of both medicines have been found in gall bladder, abdominal tissue,

skin, fat, and muscle tissues; fluids found to have therapeutic levels include synovial and peritoneal fluids, bile and pus.

Neither amoxicillin nor clavulanic acid is highly protein bound, studies show that about 13%-25% of total plasma drug content of each compound is bound to protein. From animal studies there is no evidence to suggest that either component accumulates in any organ.

Amoxicillin, like most penicillins, can be detected in breast milk. Trace quantities of clavulanate can also 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.

Reproduction studies in animals have shown that both amoxicillin and clavulanic acid penetrate the placental barrier. However, no evidence of impaired fertility or harm to the foetus was detected.

Biotransformation

Amoxicillin is also partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to 10-25% of the initial dose. Clavulanic acid is extensively metabolised in man to 2,5-dihydro-4-(2-hydroxyethyl)-5-oxo-1H-pyrrole-3-carboxylic acid and 1-amino-4-hydroxy-butan-2-one and eliminated in urine and faeces as carbon dioxide in expired air.

Elimination

As with other penicillins, the major route of elimination for amoxicillin is via the kidney, whereas for clavulanate it is by both renal and non-renal mechanisms. Approximately 60-70% of the amoxicillin and approximately 40-65% of the clavulanic acid are excreted unchanged in urine during the first 6 hours after administration of a single 500/125mg tablet or a single 500/100mg or a single 1000/200mg bolus intravenous injection.

Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid (see section 4.5 Interaction with other medicines and other forms of interaction).

5.3 Preclinical safety data

No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

AUGMENTIN vials for injection contain no excipients.

6.2 Incompatibilities

AUGMENTIN should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions. If prescribed concomitantly with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because of loss of activity of the aminoglycoside under these conditions.

AUGMENTIN solutions should not be mixed with infusions containing glucose, dextran or bicarbonate.

6.3 Shelf life

Dry powder: 2 years.

Reconstituted solution: see section 6.6 Special precautions for disposal and other handling.

6.4 Special precautions for storage

All AUGMENTIN preparations should be stored in a dry place at less than 25°C.

For storage conditions after reconstitution of the medicine, see section 6.3 Shelf life.

6.5 Nature and contents of container

AUGMENTIN 600 mg: A clear 10 mL Type I glass vial or 25 mL Type I or Type III glass vial closed with a chlorobutyl rubber Type I stopper and a tamper evidence sealing ring. Available in packs of 10 vials.

AUGMENTIN 1.2 g: A clear 25 mL Type I or Type III glass vial closed with a chlorobutyl rubber Type I stopper and a tamper evident sealing ring. Available in packs of 5 or 10 vials.

Not all strengths, pack sizes or container types may be distributed in New Zealand.

6.6 Special precautions for disposal and other handling

Intravenous route:

AUGMENTIN 600 mg: To reconstitute dissolve in 10 mL of Water for Injections B.P. (Final volume 10.5 mL).

AUGMENTIN 1.2 g: To reconstitute dissolve in 20 mL of Water for Injections B.P. (Final volume 20.9 mL).

Preparation of intravenous injections and stability		
Vial	Diluent (mL)	Volume Obtained (mL)
500/100 mg	10	10.5
1000/200 mg	20	20.9

Water for Injections B.P. is the normal diluent. A transient pink colouration may or may not develop during reconstitution. Reconstituted solutions are normally colourless or a yellow colour.

AUGMENTIN should be administered within 20 minutes of reconstitution.

Preparation of intravenous infusions and stability:

Add without delay the reconstituted solution of 500/100 mg (as prepared above – this is a minimum volume) to 50 mL of infusion fluid or of 1000/200 mg to 100mL infusion fluid (e.g. using a minibag or in-line burette).

Intravenous infusions of AUGMENTIN may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature 25°C in the recommended volumes of the following infusion fluids. If reconstituted and maintained at room temperature, infusions should be completed within the times stated.

	Stability Period 25°C
Intravenous infusion	
Water for injections BP	4 hr
Sodium Chloride intravenous infusion BP (0.9% w.v)	4 hr
Sodium Lactate Intravenous Infusion BP (M/6)	4 hr
Compound Sodium Chloride Injection BPC 1959 (Ringer's)	3 hr
Compound Sodium Lactate Intravenous Infusion BP (Ringer-Lactate:Hartmann's)	3 hr
Potassium Chloride and Sodium Chloride Intravenous Infusion BP	3 hr

The stability of AUGMENTIN intravenous solutions is concentration dependent. In the event that the use of more concentrated solutions is required, the stability period should be adjusted accordingly.

For storage at 5°C, the reconstituted solutions of 1000/200 mg and 500/100 mg may be added to pre-refrigerated infusion bags which may be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperature.

	Stability period 5°C
Intravenous infusion	
Water for Injections BP	8 hr
Sodium chloride Intravenous Infusion BP (0.9% w/v)	8 hr

AUGMENTIN is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions of AUGMENTIN may be injected into the drip tubing over a period of 3-4 minutes.

Any residual antibiotic solution should be discarded.

AUGMENTIN vials are not suitable for multi-dose use.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
NEW ZEALAND

Phone: (09) 367 2900
Facsimile: (09) 367 2910

9. DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine: 21 August 1986

10. DATE OF REVISION OF THE TEXT

14 October 2019

Summary table of changes:

Section changed	Summary of new information
4.8	Addition of new adverse reaction
	Updated copyright statement

Version: 8.0