NEW ZEALAND DATA SHEET

1. PRODUCT NAME

AUGMENTIN 125 mg/31.25 mg powder for oral suspension

AUGMENTIN FORTE 250 mg/62.5 mg powder for oral suspension

AUGMENTIN 500 mg/125 mg film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

AUGMENTIN powder for oral suspension: When reconstituted, each 5 mL contains amoxicillin trihydrate equivalent to 125 mg amoxicillin and potassium clavulanate equivalent to 31.25 mg clavulanic acid.

AUGMENTIN FORTE powder for oral suspension: When reconstituted, each 5 mL contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg clavulanic acid.

AUGMENTIN tablets: Each film coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

Excipients with known effect

AUGMENTIN and AUGMENTIN FORTE powder for oral suspension: contains 2.5 mg of aspartame per mL.

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

3. PHARMACEUTICAL FORM

AUGMENTIN: Powder for oral suspension. White to off-white powder.

AUGMENTIN FORTE: Powder for oral suspension. White to off-white powder.

AUGMENTIN tablets: White to off white, oval shaped, film coated tablets, approximately 20 mm x 9.5 mm, engraved 'AC' with a score line on one side and plain on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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 exacerbation of chronic obstructive pulmonary disease (AECOPD)/acute exacerbations of chronic bronchitis (AECB), 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

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: One AUGMENTIN tablet twice daily for mild to moderate infections. For lower respiratory tract infections, complicated urinary tract infections or severe infections at other sites, one to two AUGMENTIN 500 mg/125 mg (625 mg) tablets three times daily.

Weight based dosage recommendations for children up to 12 years and <40 kg

Lower dose (recommended for infections such as skin and soft tissue and recurrent tonsillitis): 20/5 to 40/10 mg/kg/day given as 3 divided doses.

Higher dose (recommended for infections such as otitis media, sinusitis, lower respiratory tract infections and urinary tract infections): 40/10 to 60/15 mg/kg/day given as 3 divided doses.

The usual maximum dose of AUGMENTIN is 625mg (i.e. 500mg amoxicillin + 125mg clavulanic acid) three times a day.

There is no clinical data available on doses of AUGMENTIN and AUGMENTIN FORTE powder for oral suspension higher than 40/10 mg/kg/day in children under 2 years.

Other considerations

Dose recommendations in this data sheet may be different to those in local clinical guidelines.

If a high dose of AUGMENTIN is required (for the amoxicillin component), consider combining AUGMENTIN with amoxicillin to keep the clavulanic levels within the normal therapeutic range.

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)
Tablet	No change in dosage	1 tablet 12 hourly	1 tablet once daily Dialysis decreases serum concentrations of AUGMENTIN. An additional dose may need to be supplemented at the end of dialysis.

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)
Oral Solution (in the majority of cases, parenteral therapy, where available, may be preferred).	No change in dosage	15/3.75 mg/kg given 12 hourly (maximum 500/125 mg twice daily).	15/3.75 mg/kg given as a single daily dose (maximum 500/125 mg). Dialysis decreases serum concentrations of AUGMENTIN. Prior to haemodialysis one additional dose of 15/3.75 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15/3.75 mg/kg should be administered after haemodialysis.

Hepatic impairment

Administer 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

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

The absorption of AUGMENTIN is optimised when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

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

AUGMENTIN and AUGMENTIN FORTE powder for oral suspension:

For administration of suspensions to children below 3 months, a syringe graduated to permit accurate and reproducible volumes to be dispensed, should be used.

For administration to children up to 2 years old, AUGMENTIN suspensions may be diluted to half-strength using water.

Shake well before taking each dose.

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 (see section 4.3 Contraindications). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to AUGMENTIN (see section 4.8 Undesirable effects). Drug-induced enterocolitis syndrome has been reported mainly in children receiving amoxicillin-clavulanate (see section 4.8 Undesirable effects). Drug-induced enterocolitis syndrome is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after medicinal product administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, lethargy, diarrhoea, hypotension or leucocytosis with neutrophilia. In severe cases, drug-induced enterocolitis syndrome can progress to shock. 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 may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

AUGMENTIN Suspensions contain aspartame, which is a source of phenylalanine and should be used with caution in patients with phenylketonuria.

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.

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.

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy

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 breast-fed infant.

Fertility

There are no data on the effects of amoxicillin trihydrate/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, (see section 4.4 Special Warnings and Precautions), serum sickness-like syndrome, hypersensitivity vasculitis (see also Skin and subcutaneous tissue disorders).

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.

Cardiac disorders

Very rare Kounis syndrome (see section 4.4 Special warnings and precautions for use)

Gastrointestinal disorders following oral administration to adults:

Very common: Diarrhoea

Common: Nausea, vomiting

Uncommon: Indigestion

Very Rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (see section 4.4 Special warnings and precautions for use). Black hairy tongue. Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

Gastrointestinal disorders following oral administration to paediatrics:

Common: Diarrhoea, nausea, vomiting

Uncommon: Indigestion

Very Rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis), drug-induced enterocolitis syndrome (see section 4.4 Special warnings and precautions for use). Black hairy tongue. Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

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), drug reaction with eosinophilia and systemic symptoms

(DRESS) and symmetrical drug-related intertriginous and flexanthema (SDRIFE) (baboon syndrome) (see also Immune system disorders).

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

Linear IgA disease.

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://pophealth.my.site.com/carmreportnz/s/.

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).

When present at high concentrations in urine at room temperature, amoxicillin may precipitate in bladder catheters. A regular check of potency 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 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

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

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
Listeria monocytogenes
Nocardia asteroides
Streptococcus pyogenes†*
Streptococcus agalactiae†*
*Streptococcus spp. (other β-hemolytic) *†*
*Staphylococcus aureus (methicillin susceptible)**
Staphylococcus saprophyticus (methicillin susceptible)
Coagulase negative staphylococcus (methicillin susceptible)

Gram-negative aerobes:
Bordetella pertussis
*Haemophilus 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
Streptococcus pneumoniae†*
Viridans group streptococcus
Inherently resistant organisms
Gram-negative aerobes:
Acinetobacter spp.
Citrobacter freundii
Enterobacter spp.
Hafnia alvei
Legionella pneumophila
Morganella morganii
Providencia spp.
Pseudomonas spp.
Serratia spp.
Stenotrophomas maltophilia
Yersinia enterolitica
Others:
Chlamydia pneumoniae
Chlamydia psittaci
Chlamydia spp.
Coxiella burnetti
Mycoplasma spp.

5.2 Pharmacokinetic properties

Absorption

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.

The pharmacokinetic results for two separate studies, in which AUGMENTIN 500/125 (625 mg) tablets (in comparison with the two components given separately) were administered in the fasting state to groups of healthy volunteers, are presented below.

Mean Pharmacokinetic Parameters					
Drug Administration	**Dose (mg)**	**C max (mg/L)**	**T max (hours)**	**AUC (mg.h/L)**	**T1/2 (hours)**
Amoxicillin					
AUGMENTIN 500/125 mg	500	6.5	1.5	23.2	1.3
Amoxicillin 500 mg	500	6.5	1.3	19.5	1.1
Clavulanic Acid					
AUGMENTIN 500/125 mg	125	2.8	1.3	7.3	0.8
Clavulanic acid 125 mg	125	3.4	0.9	7.8	0.7

Amoxicillin serum concentrations achieved with AUGMENTIN are similar to those produced by the oral administration of equivalent doses of amoxicillin alone.

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 500/125 mg tablet or a single 500/100 mg or a single 1000/200 mg 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 and AUGMENTIN FORTE powder for oral suspension:

Aspartame
Hydrated silica
Hypromellose
Silicon dioxide
Succinic acid
Xanthum gum
Orange dry flavour 2
Golden syrup flavour
Orange flavour
Raspberry flavour

AUGMENTIN tablets:

Core:

Magnesium stearate

Microcrystalline cellulose

Silicon dioxide

Sodium starch glycollate

Coat:

Dimeticone

Hypromellose

Macrogol 4000

Macrogol 6000

Opadry film coat

Titanium dioxide.

6.2 Incompatibilities

None known.

6.3 Shelf life

AUGMENTIN and AUGMENTIN FORTE powder for oral suspension:

Dry powder: 2 years.

Reconstituted suspension: 7 days when stored in a refrigerator (at 2°C to 8°C) (but not frozen).

AUGMENTIN tablets:

Tablets packed in blister strips sealed in a desiccant-containing foil pouch: 3 years.

Tablets packed in a cold-formed aluminium blister pack: 2 years.

6.4 Special precautions for Storage

All AUGMENTIN preparations should be stored in a dry place.

AUGMENTIN and AUGMENTIN FORTE powder for oral suspension:

Dry powder: store at or below 30°C and protect from moisture using a well-sealed container.

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

AUGMENTIN tablets:

Store below 25°C. Packed in either blister strips sealed in a desiccant-containing foil pouch or a cold-formed aluminium blister pack.

If the tablets are supplied in a blister pack sealed in a desiccant-containing foil pouch, they should be used within 30 days of the foil pouch being opened.

6.5 Nature and contents of container

AUGMENTIN powder for oral suspension:

Clear glass bottles of powder for 100 mL suspension.

AUGMENTIN FORTE powder for oral suspension:

Clear glass bottles of powder for 100 mL suspension.

AUGMENTIN tablets:

Aluminium PVC/PVdC blister strips sealed in desiccant-containing aluminium laminate pouches: 14, 20 or 21 tablets.

PVC/Aluminium/Polyamide laminate with aluminium lidding foil referred to as a cold-formed aluminium blister: 10, 12, 14, 16, 20, 24, 30, 100 or 500 tablets.

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

6.6 Special precautions for disposal and other Handling

AUGMENTIN powder for oral suspension:

To make up to 100 mL, first shake bottle to loosen powder. Then add 92 mL water and shake well. When reconstituted, each 5 mL contains amoxicillin trihydrate equivalent to 125 mg amoxicillin and potassium clavulanate equivalent to 31.25 mg clavulanic acid. When reconstituted the suspension is white to off white in colour.

AUGMENTIN FORTE powder for oral suspension:

To make up to 100 mL, first shake bottle to loosen powder. Then add 90 mL water and shake well. When reconstituted, each 5 mL contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 62.5 mg clavulanic acid. When reconstituted the suspension is white to off white in colour.

When first reconstituted, allow to stand for 5 minutes to ensure full dispersion.

Once reconstituted, the suspension must be stored in a refrigerator (at 2°C to 8°C) and used within 7 days.

For administration of suspensions to children below 3 months, a syringe graduated to permit accurate and reproducible volumes to be dispensed, should be used.

For administration to children up to 2 years old, AUGMENTIN suspensions may be diluted to half-strength using water.

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: 22 November 1983

10. DATE OF REVISION OF THE TEXT

13 February 2024

Summary table of changes:

Section changed	Summary of new information
4.8	New undesirable effects updated

Version 13.0