

DATA SHEET

AUGMENTIN[®]

Amoxicillin trihydrate/potassium clavulanate (syrups and tablets)

Presentation

AUGMENTIN Syrup 125: Glass bottles of off-white powder for the preparation of 100mL suspension. When reconstituted each 5mL contains potassium clavulanate equivalent to 31.25mg clavulanic acid with amoxicillin trihydrate equivalent to 125mg amoxicillin. When reconstituted the suspension is white/cream in colour.

AUGMENTIN Forte Syrup 250: Glass bottles of off-white powder for the preparation of 100mL suspension. When reconstituted each 5mL contains potassium clavulanate equivalent to 62.5mg clavulanic acid with amoxicillin trihydrate equivalent to 250mg amoxicillin. When reconstituted the suspension is white/cream in colour.

AUGMENTIN 500 Tablets: White to off white, oval shaped, film coated tablets, approximately 20mm x 9.5mm, engraved 'AC' with a score line on one side and plain on the other side. Each tablet contains potassium clavulanate equivalent to 125mg clavulanic acid with amoxicillin trihydrate equivalent to 500mg amoxicillin.

Pharmaceutical forms

Syrup and tablets.

Uses

Actions

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.

Pharmacodynamic properties

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

<i>In vitro</i> 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
<u>Gram-positive aerobes:</u>
<i>Bacillus anthracis</i>
<i>Enterococcus faecalis</i>
<i>Listeria monocytogenes</i>
<i>Nocardia asteroides</i>
<i>Streptococcus pyogenes</i> ^{*†}
<i>Streptococcus agalactiae</i> ^{*†}
<i>Streptococcus spp. (other β-hemolytic)</i> ^{*†}
<i>Staphylococcus aureus (methicillin susceptible)</i> *
<i>Staphylococcus saprophyticus (methicillin susceptible)</i>
<i>Coagulase negative staphylococcus (methicillin susceptible)</i>
<u>Gram-negative aerobes:</u>
<i>Bordetella pertussis</i>
<i>Haemophilus influenzae</i> *
<i>Haemophilus parainfluenzae</i>
<i>Helicobacter pylori</i>
<i>Moraxella catarrhalis</i> *

Neisseria gonorrhoeae

Pasteurella multocida

Vibrio cholerae

Other:

Borrelia burgdorferi

Leptospira icterohaemorrhagiae

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 problemGram-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 organismsGram-negative aerobes:

Acinetobacter spp.

Citrobacter freundii

Enterobacter spp.

Hafnia alvei

Legionella pneumophila

Morganella morganii

Providencia spp.

Pseudomonas spp.

Serratia spp.

Stenotrophomas maltophilia

Yersinia enterocolitica

Others:

Chlamydia pneumoniae

Chlamydia psittaci

Chlamydia spp.

Coxiella burnetti

Mycoplasma spp.

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 (625mg) tablets (in comparison with the two components given separately) were administered in the fasting state to groups of healthy volunteers, are presented below.

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

Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid (see Interactions).

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.

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.

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.

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 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.

Dosage and Administration

Dosage

Premature: No dosage recommendations can be made for this category.

Children 3-9 months: 1.25mL of AUGMENTIN Syrup 125 three times a day.

Children 9 months - 2 years: 2.5mL of AUGMENTIN Syrup 125 three times a day.

Children 2-6 years: 5mL of AUGMENTIN Syrup 125 three times a day. In severe infections this may be increased to 10mL AUGMENTIN Syrup 125 three times a day.

Children 7-12 years: 5mL of AUGMENTIN Syrup 250 three times daily. In severe infections this may be increased to 10mL of AUGMENTIN Syrup 250 three times a day.

Adults and Children 40kg and over: 1 AUGMENTIN 500 Tablet twice daily for mild to moderate infections. For lower respiratory tract infections, complicated urinary tract infections or severe infections at other sites, 1-2 AUGMENTIN 500 Tablet three times daily.

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 1.2g AUGMENTIN Intravenous given at induction of anaesthesia. Longer operations require subsequent doses of 1.2g 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.

Dosage in renal impairment:

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

	Mild Impairment (creatinine	Moderate Impairment	Severe Impairment (creatinine clearance <10mL/min)
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	clearance >30mL/min)	(creatinine clearance 10-30mL/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 of dialysis

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

	Mild Impairment (creatinine clearance >30mL/min)	Moderate Impairment (creatinine clearance 10-30mL/min)	Severe Impairment (creatinine clearance <10mL/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).	15/3.75mg/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

Dosage in 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.

Dosage in 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 above).

Administration

Oral Route (Suspensions):

Augmentin Syrup 125: To make up to 100mL, first shake bottle to loosen powder. Then add 92mL water and shake well. When reconstituted, each 5mL contains amoxicillin trihydrate equivalent to 125mg amoxicillin and potassium clavulanate equivalent to 31.25mg clavulanic acid.

Augmentin Syrup 250: To make up to 100mL, first shake bottle to loosen powder. Then add 90mL water and shake well. When reconstituted, each 5mL contains amoxicillin trihydrate equivalent to 250mg amoxicillin and potassium clavulanate equivalent to 62.5mg clavulanic acid.

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.

Shake well before taking each dose.

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.

For administrations 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.

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.

Warnings and Precautions

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 (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, AUGMENTIN therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid 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.

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 (Dosage and 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 Overdosage).

Use during pregnancy and lactation

Use in 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.

Use in Lactation: 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.

Effects on the ability to drive and operate machinery

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

Adverse 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 $\geq 1/10$, common $\geq 1/100$ and $< 1/10$, uncommon $\geq 1/1000$ and $< 1/100$, rare $\geq 1/10,000$ and $< 1/1000$, very rare $< 1/10,000$.

Infections and infestations:

Common Mucocutaneous candidiasis

Blood and lymphatic system disorders:

Rare Reversible leucopenia (including neutropenia) and thrombocytopenia
Very rare Reversible agranulocytosis and haemolytic anaemia. Prolongation of
bleeding time and prothrombin time

Immune system disorders:

Very rare Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome,
hypersensitivity vasculitis

Nervous system disorders:

Uncommon Dizziness, headache
Very rare Reversible hyperactivity and convulsions. Convulsions may occur in
patients with impaired renal function or 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) are less likely to occur after parenteral
administration.

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). 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). 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 Warnings and Precautions).

Skin and subcutaneous tissue disorders:

Uncommon	Skin rash, pruritus, urticaria
Rare	Erythema multiforme
Very rare	Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP)

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

Renal and urinary disorders:

Very rare	Interstitial nephritis, crystalluria (see Overdosage)
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Interactions

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.

Overdosage

Overdosage: 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 Warnings and Precautions).

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 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.

Pharmaceutical Precautions

Incompatibilities

None known for tablets and syrups.

Shelf life

Tablets: 36 months when stored below 25°C.

Syrup (Dry powder): 24 months when stored below 25°C.

Syrup (Reconstituted powder): 7 days when stored at 2°C to 8°C.

Special storage precautions

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

AUGMENTIN (dry powder): store below 25°C and protect from moisture using a well-sealed container.

Once reconstituted, AUGMENTIN Syrup 125 and AUGMENTIN Syrup 250 should be stored in a refrigerator (at 2°C to 8°C) (but not frozen) and used within 7 days.

AUGMENTIN Tablets, 10 tablet blister strips, are packed in sealed desiccant-containing foil pouches. The tablets should be used within 30 days of the foil pouch being opened.

Instructions for Use/Handling

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.

Medicine Classification

Prescription Medicine.

Package Quantities

AUGMENTIN 500 Tablets: Two 10-tablet blister strips (total of 20 tablets)

AUGMENTIN Syrup 125: Glass bottles of powder for 100mL suspension

AUGMENTIN Syrup 250: Glass bottles of powder for 100mL suspension

Further Information

List of excipients:

AUGMENTIN Forte Syrup 250 and AUGMENTIN Syrup 125:

Aspartame

Hydrated silica

Hypromellose

Silicon dioxide

Succinic acid

Xanthum gum

Orange dry flavour 2

Golden syrup flavour

Orange flavour

Raspberry flavour

AUGMENTIN 500 Tablets:

Core:

Magnesium stearate

Microcrystalline cellulose

Silicon dioxide

Sodium starch glycollate

Coat:

Dimeticone

Hypromellose

Macrogol 4000

Macrogol 6000

Opadry film coat

Titanium dioxide

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