

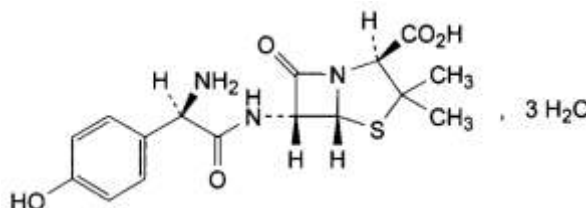
## PRODUCT INFORMATION

### NAME OF THE MEDICINE

Active ingredient: Amoxycillin (as trihydrate)

Chemical name: (2*S*,5*R*,6*R*)-6-[[*(2R)*-2-amino-2-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid

Structural formula:



Molecular formula: C<sub>16</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S·3H<sub>2</sub>O

Molecular weight: 419.5

CAS Registry No.: 61336-70-7

### DESCRIPTION

It is a white or almost white, crystalline powder, which is slightly soluble in water and in ethanol (96%) and is practically insoluble in chloroform, in ether, and in fixed oils.

Each Alphamox 250 and Alphamox 500 capsule contains amoxycillin trihydrate equivalent to 250 mg and 500 mg amoxycillin, respectively. The capsules also contain the following inactive ingredients: talc – purified, magnesium stearate, sodium starch glycolate, silica - colloidal anhydrous, sodium lauryl sulfate, gelatin, titanium dioxide, brilliant blue FCF CI42090, iron oxide yellow CI77492, cellulose – microcrystalline [Alphamox 250 only].

Each bottle of Alphamox 125 suspension contains 125 mg per 5 mL of amoxycillin when reconstituted.

Each bottle of Alphamox 250 suspension contains 250 mg per 5 mL of amoxycillin when reconstituted.

The suspensions also contain the following inactive ingredients: sodium benzoate, propylene glycol alginate, silica - colloidal anhydrous, aspartame, disodium edetate, sodium citrate, sorbitol, Raspberry Flavour Permaseal 10458-31.

### PHARMACOLOGY

#### Microbiology

Amoxycillin is similar to ampicillin in its bactericidal action against Gram-positive and Gram-negative susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of the cell wall mucopeptide.

It is active *in vitro* against most strains of *Haemophilus influenzae*\*, *Neisseria gonorrhoeae*\*, *Neisseria meningitidis*, *Escherichia coli*\*, *Proteus mirabilis*\* and *Salmonellae*. Because amoxycillin does not resist destruction by penicillinase, it is not active against penicillinase-producing organisms, particularly penicillinase-producing staphylococci.

All strains of *Pseudomonas* species, *Klebsiella* species, *Enterobacter* species, indole-positive *Proteus* species, *Serratia marcescens*, *Citrobacter* species, penicillinase producing *N. gonorrhoea* and penicillinase producing *H. influenzae* are resistant.

*In vitro* studies have demonstrated the susceptibility of most strains of the following gram-positive bacteria: alpha- and beta-haemolytic streptococci, *Diplococcus pneumoniae*, non-penicillinase producing staphylococci and *Streptococcus faecalis*. These organisms are susceptible to amoxycillin at serum concentrations, which may be expected following the recommended doses. However, some of the organisms were susceptible to amoxycillin only at concentrations achieved in the urine (see **Indications**).

*Escherichia coli* are becoming increasingly resistant to amoxycillin *in vitro* due to the presence of penicillinase-producing strains.

Strains of gonococci which are relatively resistant to benzylpenicillin may be sensitive to amoxycillin.

The following *in vitro* data are available, but their clinical significance is unknown.

<i>In vitro</i> data for amoxycillin vs. clinical pathogens	
Organism (n)	MIC90 (mcg/mL)
<i>S. pneumoniae</i> (3493) <sup>1</sup>	2
<i>H. influenzae</i> (3366) <sup>1</sup>	32
<i>S. pyogenes</i> (683) <sup>1</sup>	0.03
<i>H. influenzae</i> b-lac + (725) <sup>1</sup>	32
<i>H. influenzae</i> b-lac – (2587) <sup>1</sup>	1
<i>Klebsiella pneumoniae</i> (1161) <sup>1</sup>	32
<i>M. catarrhalis</i> (864) <sup>1</sup>	16
MSSA (1232) <sup>1</sup>	32
<i>Bacteroides fragilis</i> group (80) <sup>2</sup>	64
<i>Fusobacterium</i> sp (23) <sup>2</sup>	8
<i>Clostridium difficile</i> (21) <sup>2</sup>	2
<i>N. gonorrhoeae</i> (34) <sup>3</sup>	128

<sup>1</sup> Data from the Augmentin Global Surveillance Study: June 1999- December 2000 from USA, Canada, Brazil, Mexico, Hong Kong, Australia, France, Belgium, Italy, Netherlands, Spain, Sweden and the UK.

<sup>2</sup> Data from 1994-1995, France (Dubreuil L et al, 1996. *In vitro* evaluation of nitazoxanide and tizoxanide against anaerobes and aerobic organisms. *Antimicrob Agents Chemother.* 40(10), 2266-2270.)

<sup>3</sup> Data from 1994-1995, UK (Wise R et al, 1996. *In vitro* activity of the tricyclic  $\beta$ -lactam GV104326. *Antimicrob Agents Chemother.* 40(5), 1248-1253.)

A positive beta-lactamase test predicts resistance to penicillin, ampicillin and amoxycillin.

\* Activity refers only to betalactamase negative strains.

The following are rates of resistance to amoxycillin for common pathogens in Australia.

Rates of resistance to amoxycillin for common pathogens in Australia	
Organism	Average Resistance (%)
<i>B. fragilis</i>	100
<i>Enterobacter</i> spp.	96
<i>Klebsiella</i> spp.	98
<i>M. catarrhalis</i>	94
<i>P. aeruginosa</i>	100
<i>S. aureus</i> (methicillin-susceptible)	85
<i>Enterococcus faecalis</i>	0.2
<i>Enterococcus faecium</i>	80
<i>E. coli</i>	45.4
<i>H. influenzae</i>	20.3
<i>P. mirabilis</i>	14
<i>S. pneumoniae</i>	0.6 (fully resistant)

### Microbiology, Breakpoints

*Streptococcus pneumoniae*: S  $\leq$  -2 mcg/mL; I = 4 mcg/mL; R  $\geq$  8 mcg/mL

Note: because amoxycillin has greater *in vitro* activity against *S. pneumoniae* than does ampicillin, the majority of *S. pneumoniae* strains with intermediate susceptibility to ampicillin are fully susceptible to amoxycillin.

### Microbiology, Susceptibility Tests

**Dilution or Diffusion Techniques.** Either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (eg. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of “Susceptible” indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of “Intermediate” indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to the alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of the drug can be used. This category also provides a buffer zone, which prevent small uncontrolled technical factors from causing major discrepancies in interpretation. A report of “Resistant” indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

**Note:** The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections. This information gives only an approximate guidance on probabilities whether organisms will be susceptible to amoxycillin.

**Cross-Resistance.** Other beta-lactams, beta-lactam/beta-lactamase inhibitor combinations and cephalosporins.

**Resistance Mechanisms.** Production of penicillinase, altered penicillin binding proteins.

### Pharmacokinetics

Alphamox is stable in the presence of gastric acid and is rapidly and well absorbed after oral administration, even in the presence of food.

Amoxycillin diffuses rapidly into most body tissues and fluids, with the exception of brain and spinal fluid

except when meninges are inflamed.

Amoxycillin has been shown to diffuse into sputum and saliva and is excreted mainly via the urine where it exists in a high concentration.

The amount to be found in the bile is variable, depending on normal biliary secretory function. The half-life of amoxycillin is 61.3 minutes with normal renal function, and in the absence of renal function 16 to 20 hours.

Amoxycillin is excreted in the urine both unchanged and as penicilloic acid. About 75% of a 1g dose is excreted in the urine in 6 hours in the presence of normal renal function (60% as amoxycillin and 15% as penicilloic acid). However, only 32% of a 3g dose is excreted via the urine as the biologically active component in 8 hours (by which time most of the urinary excretion is complete). This proportional difference in the amount excreted from the different doses reflects a lack of linearity between doses and extent of absorption with a levelling off at higher doses of oral amoxycillin.

Excretion of Alphamox can be delayed by concurrent administration of probenecid, thus prolonging its therapeutic effect.

Amoxycillin is not highly protein bound, being only 17% protein bound in serum as measured by ultrafiltration or equilibrium dialysis. The average peak serum levels resulting from the oral administration of 250 mg and 500 mg amoxycillin are 5 mcg/mL and 6.6 to 10.8 mcg/mL respectively, occurring one to two hours after administration. Measurable serum levels of amoxycillin are present eight hours after administration of a single oral dose.

## INDICATIONS

Treatment of the following infections due to susceptible strains of sensitive organisms.

*Note.* Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxycillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results.

- *Skin and Soft Tissues*  
Staphylococcus, non-penicillinase producing; Streptococcus.
- *Respiratory (Acute and Chronic)*  
*H. influenzae*; Streptococcus; *S. pneumoniae*; staphylococcus, non-penicillinase producing.
- *Genitourinary Tract (complicated and uncomplicated, Acute and Chronic)*  
*P. mirabilis* and *E. faecalis*.
- *Gonorrhoea*  
*N. gonorrhoea* (non-penicillinase producing).
- *Prophylaxis of Endocarditis*  
Amoxycillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with a prosthetic heart valve or those who have previously had endocarditis.

## CONTRAINDICATIONS

Amoxycillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. penicillins, cephalosporins).

## PRECAUTIONS

Serious, and occasionally fatal, hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy. Before commencing therapy with any penicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, appropriate therapy should be instituted and Alphamox therapy discontinued.

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, should also be administered as indicated.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including amoxycillin. A toxin produced with *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases, appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated.

Drugs which delay peristalsis, e.g. opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition and should not be used.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxycillin 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.

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy.

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*), the drug should be discontinued and/or appropriate therapy instituted.

Amoxycillin, an aminopenicillin, 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 amoxycillin is used.

Amoxycillin should be given with caution to patients with lymphatic leukaemia, since they are especially susceptible to ampicillin-induced skin rashes.

Following single dose therapy of acute lower urinary tract infections, the urine should be cultured. A positive culture may be evidence of a complicated or upper urinary tract infection and call for a longer or larger course of therapy.

Adequate fluid intake and urinary output must be maintained in patients receiving high doses of amoxycillin.

Dosage should be adjusted in patients with renal impairment (see **Dosage and Administration**).

### Use in Pregnancy (Category A)

Animal studies with amoxycillin have shown no teratogenic effects. Amoxycillin has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies.

Amoxycillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

*Australian categorisation definition of Category A.* Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

*Labour and Delivery.* Oral ampicillin class antibiotics are generally poorly absorbed during labour. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions and duration of contractions. However, it is not known whether the use of amoxycillin in humans during labour or delivery has immediate or delayed adverse effects on the foetus, prolongs the duration of labour or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

### Use in Lactation

Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when amoxycillin is administered to breastfeeding women.

### Effects on Laboratory Tests

Oral administration of amoxycillin will result in high urine concentrations of amoxycillin. Since high urine concentrations of amoxycillin may result in false positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix or Testape) be used.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated oestriol, oestriol-glucuronide, conjugated oestrone and oestradiol has been noted. This effect may also occur with amoxycillin.

## INTERACTIONS WITH OTHER MEDICINES

Probenecid decreases the renal tubular secretion of amoxycillin. Concurrent use with Alphamox may result in increased and prolonged blood levels of amoxycillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs 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. Similar reactions can be expected with amoxycillin.

In common with other broad-spectrum antibiotics, amoxycillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

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

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxycillin.

## ADVERSE EFFECTS

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins.

The following adverse reactions have been reported as associated with the use of amoxycillin:

*Infections and infestations.* Mucocutaneous candidiasis have been reported very rarely.

*Gastrointestinal.* Nausea, vomiting, diarrhoea, intestinal candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely. Black hairy tongue has been reported very rarely (see **Precautions**).

*Hypersensitivity Reactions.* Erythematous maculopapular rashes, urticaria and, pruritus have been reported occasionally. Rarely, skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous, exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP) have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and intestinal nephritis have been reported rarely.

Whenever such reactions occur, Alphamox should be discontinued. (Note: Urticaria, other skin rashes and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids). Anaphylaxis is the most serious reaction experienced (see **Precautions**).

*Hepatic.* A moderate rise in AST and/or ALT has been noted, but the significance of this finding is unknown. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

*Haemic and Lymphatic Systems.* Reactions such as anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia and leucopenia (including severe neutropenia or agranulocytosis) have been reported during therapy with other penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Prolongation of bleeding time and prothrombin time have also been rarely reported.

*Central Nervous System Effects.* CNS effects have been seen rarely. They include hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

*Miscellaneous.* Superficial tooth discolouration has been reported vary rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

## DOSAGE AND ADMINISTRATION

The following recommended doses are for patients with normal renal function.

### Upper Respiratory Tract Infections, Genitourinary Tract Infections, Skin and Soft Tissue Infections

*Adults.* 250 mg every 8 hours.

*Children (under 20 kg).* 20 mg/kg/day in equally divided doses every 8 hours.

In severe infections or those caused by less susceptible organisms, 500 mg every 8 hours for adults and 40 mg/kg/day in equally divided doses every 8 hours for children may be needed.

### Lower Respiratory Tract Infections

*Adults.* 500 mg every 8 hours.

*Children (under 20 kg).* 40 mg/kg/day in equally divided doses every 8 hours.

### Urethritis, Gonococcal

*Adults.* 3 grams as a single dose.

Cases of gonorrhoea with a suspected lesion of syphilis should have darkfield examinations before receiving Alphamox and monthly serological tests for a minimum of four months.

### Acute, Uncomplicated Lower Urinary Tract Infections in non-pregnant adult females

*Adults.* 3 grams as a single dose.

*Note:* Experience in neonates is too limited to make any recommendations regarding dosage or the appropriateness of the oral route.

The children's dosage is intended for individuals whose weight will not cause dosage to be calculated greater than

that recommended for adults. Children weighing more than 20 kg should be dosed according to adult recommendations.

#### Renal Impairment

The excretion of the antibiotic will be delayed, and depending on the degree of impairment, it may be necessary to reduce the total daily dosage.

In patients receiving peritoneal dialysis, the maximum recommended dose is 500 mg/day. Amoxycillin may be removed from the circulation by haemodialysis.

It should be recognised that in the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisals are necessary. Smaller doses than those recommended above should not be used. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days treatment for any infection caused by haemolytic Streptococci to prevent the occurrence of rheumatic fever or glomerulonephritis.

#### Prophylaxis of Endocarditis

See table overleaf.



### Prophylaxis of Endocarditis

#### Based on the recommendations of the British Society for Antimicrobial Chemotherapy

Condition		Adults' Dosage (including elderly)	Children's Dosage	Notes
<p><i>Dental Procedures.</i> Prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues, and who have not received a penicillin in the previous month.</p> <p>(N.B. Patients with prosthetic heart valves should be referred to hospital- see below).</p>	Patient not having general anaesthetic.	<p>Amoxycillin 3 grams orally, 1 hour before procedure.</p> <p>A second dose may be given 6 hours later, if considered necessary.</p>	<p>Under 10 years: Half adult dose.</p> <p>Under 5 years: Quarter adult dose.</p>	<p><i>Note 1.</i> Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin.</p>
	Patient having general anaesthetic: oral antibiotics not appropriate.	Amoxycillin 1 gram IM immediately before induction; with 500 mg orally, 6 hours later.	Under 10 years: Half adult dose.	
<p><i>Dental Procedures.</i> Patients for whom referral to hospital is recommended:</p> <p>(a) patients to be given a general anaesthetic who have been given a penicillin in the previous month.</p> <p>(b) patients to be given a general anaesthetic who have a prosthetic heart valve.</p> <p>(c) patients who have had one or more attacks of endocarditis.</p>		<p>Initially: Amoxycillin 1 gram IM with 120mg gentamicin IM, immediately prior to anaesthesia (if given) or 15 minutes prior to dental procedure.</p> <p>Followed by (6 hours later): Amoxycillin 500 mg orally.</p>	Under 10 years: The doses of Amoxycillin should be half the adult dose. The dose of gentamicin should be 2mg/kg.	<p><i>Note 2.</i> Please consult the appropriate data sheet for full prescribing information on gentamicin and administration instructions for amoxycillin IM.</p>
<p><i>Genito-urinary Surgery or Instrumentation.</i> Prophylaxis for patients who have no urinary tract infection and who are to have genito-urinary surgery or instrumentation under general anaesthesia.</p> <p><i>Obstetric and Gynaecological Procedures and Gastro-intestinal Procedures.</i> Routine prophylaxis is recommended only for patients with prosthetic heart valves.</p>		<p>Initially: Amoxycillin 1 gram IM with 120mg gentamicin IM, immediately before induction.</p> <p>Followed by (6 hours later): Amoxycillin 500 mg orally or IM according to clinical condition.</p>	Under 10 years: The doses of Amoxycillin should be half the adult dose. The dose of gentamicin should be 2mg/kg.	See Notes 2 above.
<p><i>Surgery or Instrumentation of the Upper Respiratory Tract</i></p>	Patients other than those with prosthetic heart valves.	<p>Amoxycillin 1 gram IM immediately before induction.</p> <p>Followed by (6 hours later): Amoxycillin 500 mg IM.</p>	Under 10 years: Half adult dose.	<p><i>Note 3.</i> The second dose of Amoxycillin may be administered orally as syrup.</p>
	Patients with prosthetic heart valves.	<p>Initially: Amoxycillin 1 gram IM with 120mg gentamicin IM, immediately before induction.</p> <p>Followed by (6 hours later): Amoxycillin 500 mg IM.</p>	Under 10 years: The dose of Amoxycillin should be half the adult dose. The gentamicin dose should be 2mg/kg.	See Notes 2 and 3 above.

## OVERDOSAGE

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water/electrolyte imbalance should be treated symptomatically. During the administration of high doses of amoxycillin, adequate fluid intake and urinary output must be maintained to minimise the possibility of amoxycillin crystalluria.

Amoxycillin can be removed from the circulation by haemodialysis.

For further advice on the management of overdose or suspected overdose, contact the Poisons Information Centre on 13 11 26.

## PRESENTATION AND STORAGE CONDITIONS

<b>Alphamox 250,</b>	amoxycillin 250 mg capsule: cream body, green cap; blister pack 20, 30*s; bottle 4*, 20*, 500s*.
<b>Alphamox 500,</b>	amoxycillin 500 mg capsule: cream body, green cap; blister pack 20, 30*, 28*, 6s*; bottle 4*, 20*, 500s*.
<b>Alphamox 125,</b>	amoxycillin 125 mg/5mL powder for oral suspension: white to cream coloured, raspberry flavoured, sugar free; 100mL when reconstituted.
<b>Alphamox 250,</b>	amoxycillin 250 mg/5mL powder for oral suspension: white to cream coloured, raspberry flavoured, sugar free; 100mL when reconstituted.

\* Not marketed in Australia.

Store capsules and powder below 25°C.

After reconstitution, sugar free suspension should be stored at 2 to 8°C and used within 14 days. Discard remaining portion thereafter.

### Reconstitution

For 125 mg/5mL suspension, add 90 mL of water in small quantities.

For 250 mg/5mL suspension, add 80 mL of water in small quantities.

Shake vigorously. Shake well before use.

Refrigerate prepared mixture. Do not freeze.

## POISON SCHEDULE OF THE MEDICINE

S4 – Prescription Only Medicine

## NAME AND ADDRESS OF THE SPONSOR

**Alphapharm Pty Limited**

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## **DATE OF APPROVAL**

*Approved by the Therapeutic Goods Administration on 8 February 2006.*

*Date of most recent amendment: 21 December 2011*