PRODUCT INFORMATION
MAXAMOX®
500mg/5mL POWDER FOR ORAL SUSPENSION

NAME OF THE MEDICINE

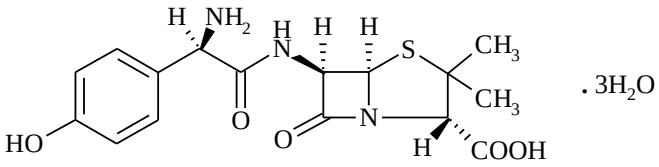
Active Ingredient: Amoxycillin trihydrate

Inactive Ingredients: Anhydrous citric acid, sodium benzoate, aspartame, purified talc, sodium citrate anhydrous, guar gum, silicon dioxide, lemon flavouring, peach-apricot flavouring and orange flavouring.

DESCRIPTION

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

Structural Formula:



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

Molecular Formula: $C_{16}H_{19}N_3O_5S.3H_2O$

Molecular Weight: 419.4

CAS Number: 61336-70-7

PHARMACOLOGY

Microbiology

Amoxycillin trihydrate is a broad-spectrum penicillin similar to ampicillin in its bactericidal action. It is believed to act through the inhibition of biosynthesis of cell wall mucopeptide. It is active against both gram-positive and gram-negative microorganisms. Amoxycillin is active *in vitro* against beta-lactamase negative strains of *Proteus mirabilis*, and *Haemophilus influenza*. *In vitro* studies have also demonstrated activity against most strains of alpha- and beta-haemolytic streptococci, *Streptococcus pneumoniae*, and beta-lactamase negative strains of staphylococci, *Neisseria gonorrhoeae, Neisseria meningitidis and Enterococcus faecalis*. However, some of the organisms are sensitive to amoxycillin only at concentrations achieved in the urine. Strains of gonococci which are relatively resistant to benzyl penicillin may also be resistant to amoxycillin. Amoxycillin is not effective against penicillinase producing bacteria, particularly resistant staphylococci which now have a high prevalence. All strains of Pseudomonas, Klebsiella,

Enterobacter, indole positive Proteus, *Serratia marcescens*, Citrobacter, penicillinase producing *N. gonorrhoeae* and penicillinase producing *H. influenzae* are also resistant. *Escherichia coli* isolates are becoming increasingly resistant to amoxycillin *in vitro* due to the presence of penicillinase-producing strains.

Acquired resistance for amoxycillin in Australia*

ORGANISM	% RESISTANT STRAINS
S. pneumoniae	16.8% intermediate resistance; 8.6% resistant
H. influenzae	20.3%
M. catarrhalis	94.0%
B. fragilis	100%
Enterobactor spp.	96%
Klebsiella spp.	98%
P. aeruginosa	100%
S. aureus (methicillin-susceptible)	85%
Enterococus faecalis	0.2%
Enterococcus faecium	80%
E. coli	45.4%
P. mirabilis	14%

**Therapeutic Guidelines Antibiotic 2000 Edition*

Disc Susceptibility Testing
Dilution of diffusion techniques. Either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. 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 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 drug can be used. This category also provides a buffer zone, which prevents 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 may 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.

Pharmacokinetics
Amoxycillin is stable in the presence of gastric acid and is rapidly and well absorbed after oral administration, even in the presence of food. Peak serum levels are reached within one to two hours after ingestion. Amoxycillin readily distributes in most body tissues and fluids with the exception of brain and spinal fluid except when the 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. Concentrations in the bile vary and are dependant upon normal biliary function. Amoxycillin is eliminated with a half-life of 61.3 minutes with normal renal function and up to 16-20 hours in the absence of renal function. Amoxycillin is excreted in the urine as unchanged drug and as penicilloic acid. Approximately 75% of a 1g dose is excreted in the urine within six hours with normal renal function. However, there is a proportional difference in the amount excreted following different doses, due to lack of linearity in the rate of absorption with higher doses. Elimination of amoxycillin can be delayed by concurrent administration of probenecid. Amoxycillin is only 17% protein bound in serum.

Orally administered doses of amoxycillin 250 and 500 mg result in average peak serum levels one to two hours after administration of 5 microgram/mL and 10.25 microgram/mL respectively. Detectable serum levels of amoxycillin are present eight hours after ingestion of a single dose.

Clinical Trials
The clinical efficacy of amoxycillin 30 mg/kg twice daily versus 15 mg/kg three times daily dosage regimen in the treatment of acute otitis media (AOM) in children was determined in a large double-blind, randomised, multicentre study. 516 patients were included in the study and treated for 8 to 10 days. Patients were assessed during therapy (days 3 – 5), after end of therapy (days 12 – 14) and at follow-up (days 38 – 46).

The primary efficacy variable for the study was clinical response rate at the end of therapy (days 12 - 14) and the secondary efficacy variable was clinical success rate and recurrence rate at follow-up (days 38 – 46).

A total of 515 subjects aged from 6 months to 12 years received treatment and were included in the intent-to-treat population. 166 (51.6%) were male, mean (SD) age was 4.080 (2.649) years, mean (SD) body weight 17.864 (8.489) kg and 509 (98.6%) were white. Compliance with the dose regimens was ≥80.0% for over 90.0% subjects.

For clinically evaluable patients, the results are shown in the following table:

	Amoxycillin 30 mg/kg 2x daily	**Amoxycillin 15 mg/kg 3x daily**	**95% CI**	**Comparison X^2 Test**
Clinical success rate at end of therapy (days 12-14)	183/189 (96.8%)	182/185 (98.4%)	-4.6, 1.5	p-value=0.327
Clinical recurrence at follow-up (days 38-46)	15/183 (8.2%)	11/182 (6.0%)	-3.1, 7.4	p-value=0.424
Overall success rate at follow-up (days 38-46)	168/189 (88.9%)	171/185 (92.4%)	-9.4, 2.3	p-value=0.239

No significant differences in the efficacy results between the two dosage regimens and the 95% confidence intervals (CI) confirm the non-inferiority of the twice daily dosage regimen.

Limited bacteriological results were reported in this study.

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. Amoxycillin alone or in combination with another antibiotic, may be used in an emergency where the causative organism has not been identified.

- Respiratory tract infections (acute and chronic) including acute otitis media (AOM): *H. influenzae*; Streptococcus*; S. pneumoniae*; Staphylococcus, nonpenicillinase producing; *E. coli* (see Microbiology).

- Urogenital infections (complicated and uncomplicated, acute and chronic): *E. coli* (see Microbiology), *P. mirabilis and Strep. faecalis*.

- Gonorrhoea: *N. gonorrhoeae* (nonpenicillinase producing).

- Skin and skin structure infections: Staphylococcus, nonpenicillinase producing; Streptococcus; *E. coli* (see Microbiology).

- 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.

Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G.

CONTRAINDICATIONS

Amoxycillin is a penicillin and should not be given to patients with a history of hypersensitivity to β-lactam antibiotics (e.g. penicillins, cephalosporins, carbapenem or monobactam). Known and suspected hypersensitivity to penicillins. Potential cross allergy to other beta lactams such as cephalosporins should be taken into account.

Known hypersensitivity to the active substance, to any of the penicillins or to any of the excipients.

Antibiotics have no place in trivial infections.

PRECAUTIONS

Serious, and occasionally fatal, hypersensitivity (anaphylactoid) reactions have been reported in patients receiving penicillin therapy. These reactions are more frequently associated with parenteral therapy but have been reported for patients receiving oral penicillins. Careful assessment should be made prior to administration of amoxycillin to determine any previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. Amoxycillin therapy should be immediately discontinued if hypersensitivity reactions occur. Serious anaphylactoid reactions should be treated

with adrenaline. Oxygen, intravenous steroids and airways management, including intubation should be administered as necessary.

Non-susceptible microorganisms: Amoxycillin is not suitable for the treatment of some types of infection unless the pathogen is already documented and known to be susceptible or there is a very high likelihood that the pathogen would be suitable for treatment with amoxycillin. This particularly applies when considering the treatment of patients with urinary tract infections and severe infections of the ear, nose and throat.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including amoxycillin. A toxin produced by *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). If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further. 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 eg. 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.

Patients should be told about the potential occurrence of allergic reactions and instructed to report them.

If allergic reactions occur, the drug should be discontinued and the usual treatment with adrenaline, antihistamines and corticosteroids should be instituted, as necessary.

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. The possibility of superinfection with mycotic or bacterial pathogens should be kept in mind. If superinfection occurs (usually involving Aerobacter, Pseudomonas or Candida) discontinue the drug and/or institute appropriate therapy.

Elevated liver enzymes and changes in blood counts have been reported.

Amoxycillin should be given with caution to patients with lymphatic leukaemia as they are susceptible to amoxycillin induced skin rashes.

Jarisch-Herxheimer reaction: The Jarisch-Herxheimer reaction has been seen following amoxycillin treatment of Lyme disease. It results directly from the bactericidal activity of amoxycillin on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.

Amoxycillin should not be used for the treatment of bacterial infections in patients with viral infections, presenting with sore throat, pharyngitis or infectious mononucleosis, as a high incidence of amoxycillin induced erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving amoxycillin.
Special caution should be exercised in patients with allergic diatheses or bronchial asthma and hay fever.

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 higher dose or prolonged course of treatment may be appropriate.

The presence of high urinary concentrations of amoxycillin can cause precipitation of the product in urinary catheters. Therefore, catheters should be visually inspected at intervals.

At high doses, adequate fluid intake and urinary output must be maintained to minimise the possibility of amoxycillin crystalluria.

Fertility
There are no data on the effects of amoxycillin on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

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.

Precaution should be taken in premature children and during neonatal period: renal, hepatic and haematological functions should be monitored.

As with other beta-lactams, the blood formula should be checked regularly during high-dose therapy.

High dose therapy with beta-lactams for patients with renal insufficiency or seizures history, treated epilepsy and meningeal affection, could exceptionally lead to seizures. Dosage should be adjusted in patients with renal impairments (see DOSAGE AND ADMINISTRATION).

The occurrence of a generalized erythema with fever and pustules at the beginning of treatment should make suspect a generalized acute exanthematic pustulosis; this necessitates the interruption of therapy and contraindicated any further administration of amoxycillin.

Use in Pregnancy
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.

Animal studies with amoxycillin have shown no teratogenic effects. The product 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.

Use in 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 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 breast milk and caution should be exercised when amoxycillin is administered to nursing mothers. So far no detrimental effects for the breast-fed infant have been reported after taking amoxycillin. Amoxycillin can be used during breast-feeding. However, breast-feeding must be stopped if gastrointestinal disorders (diarrhoea, candidosis or skin rash) occur in the new born

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 enzyme-based glucose oxidase reactions (such as Clinistix, or Testape) be used

INTERACTIONS WITH OTHER MEDICINES

Allopurinol
Concomitant ingestion of allopurinol and ampicillin may promote the occurrence of skin rashes. The underlying mechanism is still poorly understood. Similar reactions can be expected with amoxycillin.

Digoxin
An increase in the absorption of digoxin is possible on concurrent administration with amoxycillin. A dose adjustment of digoxin may be necessary.

Anticoagulants
Concomitant administration of amoxycillin and anticoagulants from the coumarin class, may prolong the bleeding time. A dose adjustment of anticoagulants may be necessary (See Precautions). If coadministration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxycillin.

A large number of cases showing an increase of oral anticoagulant activity has been reported in patients receiving antibiotics. The infectious and inflammatory context, age and the general status of the patient appear as risk factors. In these circumstances, it is difficult to know the part of the responsibility between the infectious disease and its treatment in the occurrence of INR disorders. However, some classes of antibiotics are more involved, notably fluoroquinolones, macrolides, cyclines, cotrimoxazole and some cephalosporins

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 co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxycillin.

Methotrexate
Interaction between amoxycillin and methotrexate leading to methotrexate toxicity has been reported. Serum methotrexate levels should be closely monitored in patients who receive amoxycillin and methotrexate simultaneously (see Precautions). Amoxycillin decreases the renal clearance of methotrexate, probably by competition at the common tubular secretion system.

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

Probenecid
Concomitant use of probenecid is not recommended. The concomitant administration of probenecid produces sustained and higher plasma levels by reducing renal elimination of amoxycillin.

Oral administration of amoxycillin will result in high urine concentrations of amoxycillin. Since high urine concentrations of ampicillin 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 enzyme based glucose oxidase reactions (such as Clinistix or Testape) be used.

Caution is recommended when amoxycillin is given concomitantly with:

Oral hormonal contraceptives
Administration of amoxycillin can transiently decrease the plasma level of oestrogens and progesterone, and may reduce the efficacy of oral contraceptives. It is therefore recommended to take supplemental non-hormonal contraceptive measures.

Other forms of interactions:

- Forced diuresis leads to a reduction in blood concentrations by increased elimination of amoxycillin
- Amoxycillin may decrease the amount of urinary estriol in pregnant women.
- At high concentrations, amoxycillin may diminish the results of serum glycemia levels.
- Amoxycillin may interfere with protein testing when colormetric methods are used

ADVERSE EFFECTS

Amoxycillin 30 mg/kg twice daily versus 15mg/kg three times daily dosage regimen were compared in a large double-blind, randomised, multicentre study of 516 children with acute otitis media (AOM). 515 patients were evaluable for safety analysis. One or more drug-related adverse events (AEs) were reported in 14.3% (37/259) of b.i.d. and in 11.7% (30/256) of t.i.d. patients (95% CI -3.2%, 8.4%). The most frequently reported drug-related AEs in each group were gastrointestinal symptoms (b.i.d. 11.3 % vs. t.i.d. 9.8 %, 95% CI -4.8%, 7.9%), which were mainly of mild or moderate severity. 12 b.i.d. (4.6%) and 15 t.i.d. patients (5.9%) discontinued therapy prematurely because of the occurrence of AEs. Six serious AEs were reported (4 b.i.d., 2 t.i.d.) although none of these events were related to the study medication.

The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and skin rash. The tables below provide a listing of the adverse events reported in the evaluable study population and the subgroup of patients ≤ 2 years of age.

Table 1: Adverse Events in the Safety Evaluable Study Population

Adverse event	**30 mg/kg b.i.d.**	**15 mg/kg t.i.d.**
Total no. of patients evaluable for safety	*259*	*256*
No. of patients with AEs (%)	113 (43.6)	101 (39.5)
No. of patients with drug-related AEs (%)	37 (14.3)	30 (11.7)
Total number of AEs	*212*	*153*
No. of drug-related AEs (%)	44 (20.7)	30 (19.6)
Gastrointestinal AEs (%)	24 (11.3)	15 (9.8)
Rash (%)	13 (6.1)	10 (6.5)
Diarrhoea (%)	14 (6.6)	6 (3.9)
Vomiting (%)	5 (2.3)	2 (1.3)
Candidiasis (%)	4 (1.9)	1 (0.6)
Abdominal pain (%)	0	2 (1.3)

Table 2: Adverse Events in the Safety Evaluable Study Population (patients ≤ 2 years of age)

Adverse event	**30 mg/kg b.i.d.**	**15 mg/kg t.i.d.**
Total no. of patients evaluable for safety	*64*	*60*
No. of patients with AEs (%)	33 (51.6)	37 (61.7)
No. of patients with drug-related AEs (%)	11 (17.2)	13 (21.7)
Total number of AEs (%)	*61*	*52*
No. of drug-related AEs (%)	15 (24.6)	14 (26.9)
Gastrointestinal AEs (%)	7 (11.5)	7 (13.5)
Rash (%)	7 (11.5)	4 (7.7)
Diarrhoea (%)	5 (8.2)	3 (5.8)
Vomiting (%)	1 (1.6)	1 (1.9)
Candidiasis (%)	1 (1.6)	1 (1.9)

The results show no significant differences in the tolerability of the two dosage forms.

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

Gastrointestinal. Nausea, vomiting, diarrhoea. Intestinal candidiasis, antibiotic associated colitis (including pseudomembranous colitis and haemorrhagic colitis) superficial discoloration

of the teeth (especially with the suspension) have been reported rarely (see Precautions). Usually the discoloration can be removed by teeth brushing. If severe and persistent diarrhoea occurs, the very rare possibility of pseudomembranous colitis should be considered. The administration of anti-peristaltic drug is contraindicated. Black hairy tongue and haemorrhagic colitis have been reported very rarely.

Hypersensitivity. Erythematous maculopapular rash, pruritus and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme exsudativum, acute generalised exanthematous pustulosis (AGEP), lyells syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, Jarisch-Herxheimer reaction and bullous and exfoliative dermatitis have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and interstitial nephritis (crystalluria) have been reported rarely. Whenever such reactions occur, amoxycillin 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 occasionally 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 reported rarely.

Renal and urinary tract disorders.
Interstitial nephritis, crystalluria (see Overdosage) have been reported very rarely.

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.

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

Miscellaneous. 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.

DOSAGE AND ADMINISTRATION

Normal renal function:

Upper respiratory tract infections; genitourinary tract infections; skin and soft tissue infections:

Adults: 250 mg every eight 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 eight hours for adults and 40 mg/kg/day in equally divided doses every 8 hours for children may be needed.

Acute otitis media (AOM):

Children (6 months to 12 years old) 30 mg/kg twice daily (to a maximum dose of 1 g twice daily).

Treatment should be continued for 48 to 72 hours after the child becomes asymptomatic.

Lower respiratory tract infections:

Adults: 500 mg every eight hours
Children (under 20 kg): 40 mg/kg/day every 8 hours in equally divided doses

Urethritis, gonococcal:

Adults: 3 g as a single dose.

Cases of gonorrhoea with a suspected lesion of syphilis should have darkfield examinations before receiving amoxycillin and monthly serological tests for a minimum of 4 months.

Acute, uncomplicated lower urinary tract infections in non-pregnant adult females:

3 g as a single dose.

Use in neonates:

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

Use in children:

The children's dosage is intended for individuals whose weight will not cause dosage greater than that recommended for adults. Children receiving amoxycillin every 8 hours and weighing more than 20 kg should receive the adult recommended doses.

The maximum weight for children receiving 12 hourly dosing is approximately 35 kg.

Impaired renal function:

In 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 dose.

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

Chronic urinary tract infections:

Frequent biological and clinical appraisals are recommended for patients under treatment for chronic urinary tract infections. Doses smaller than those recommended should not be used. Therapy for stubborn infections may have to be extended for several weeks.

Bacteriological and clinical appraisals may have to be continued for several months following cessation of treatment.

Duration of treatment:
Treatment should be continued for a minimum of 48 to 72 hours beyond the time when patients become asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be a minimum of 10 days treatment for any infection caused by haemolytic streptococci to prevent occurrence of acute rheumatic fever or glomerulonephritis.

Prophylaxis of endocarditis:
Dental Procedures. Prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues, who are not having general anaesthetic, and who have not received a penicillin in the previous month. (*Note*: Patients with prosthetic heart valves should be referred to hospital.)

Adults (including elderly): 3g orally, 1 hour before procedure. A second dose may be given 6 hours later if considered necessary.

Children:	*Under 10 years*:	Half adult dose
	Under 5 years:	Quarter adult dose

(*Note*: Prophylaxis with alternative antibiotics should be considered if the patient has received penicillin within the previous month, or is allergic to penicillin.)

OVERDOSAGE

Signs of overdosage of amoxycillin would predominantly be gastrointestinal related. The symptoms may include abdominal or stomach cramps and pain, severe nausea, vomiting or diarrhoea. Treatment of penicillin overdosage should be symptomatic and supportive. Haemodialysis may aid in the removal of penicillins from the blood.

Please also refer to Precautions and Adverse Reactions.

PRESENTATION AND STORAGE CONDITIONS

Maxamox Powder for Oral Suspension is a white to slightly yellowish powder containing 500mg/5mL amoxycillin (as trihydrate). It is available in 100 mL bottles.

Powder:	Store below 25°C. Keep the container tightly closed.
After Mixing:	Store in a refrigerator (2°C- 8°C). Discard unused suspension after 14 days.

NAME AND ADDRESS OF THE SPONSOR

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

POISON SCHEDULE OF THE MEDICINE: S4

DATE OF FIRST INCUSION ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG): 22nd May 2008

DATE OF MOST RECENT AMENDMENT: 11/04/2016