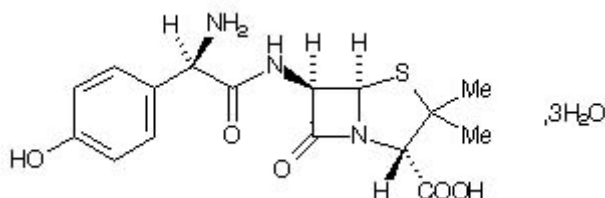


**APO- AMOXYCILLIN CAPSULES****NAME OF THE MEDICINE**

Amoxycillin (as amoxycillin trihydrate).

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.

Structural Formula:



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

Molecular Weight: 419.4

CAS Registry Number: 61336-70-7

**DESCRIPTION**

Amoxycillin trihydrate is a white or almost white, crystalline powder, slightly soluble in water and in alcohol.

Amoxycillin trihydrate is a semisynthetic antibiotic and is a member of the penicillinase-stable group of penicillins derived from the penicillin nucleus, 6-aminopenicillanic acid, isolated at Beecham Research Laboratories.

**PHARMACOLOGY****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. Amoxycillin diffuses rapidly into 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.

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 is 16 to 20 hours.

Amoxycillin is excreted in the urine both unchanged and as penicilloic acid. About 75% of a 1 g dose is excreted in the urine in 6 hours in the presence of normal renal function (60% is biologically active and 15% is penicilloic acid). However about 32% of a 3 g 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 amoxycillin 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.

Orally administered doses of 250 and 500 mg result in average peak serum levels 1 to 2 hours after administration of 5 µg/mL and 6.6–10.8 µg/mL respectively. Detectable serum levels of amoxycillin are present 8 hours after ingestion of a single dose.

### 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*\*, *N. 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. gonorrhoeae* and penicillinase-producing *H. influenzae* are resistant. *In vitro* studies have demonstrated the susceptibility of most strains of the following gram-positive bacteria: α- and β-haemolytic streptococci, *Diplococcus pneumonia*, 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**).

\*Activity refers only to β-lactamase negative strains.

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

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

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

#### *In vitro* data for amoxycillin vs. clinical pathogens

Organism (n)	MIC90 (µg/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 1994-995, France (Dubreuil L et al, 1996. *In vitro* evaluation of netazoxanide 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 β-lactam GV104326. *Antimicrob Agents Chemother.* 40(5), 1248-1253).

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

**Rates of Resistance to Amoxycillin for Common Pathogens in Australia**

<b>Organism</b>	<b>Average % resistance</b>
<i>B. fragilis</i>	100
Enterobacter spp.	96
Klebsiella spp.	98
<i>M. catarrhalis</i>	84
<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. influenza</i>	20.3
<i>P. mirabilis</i>	14
<i>S. pneumoniae</i>	0.6 (fully resistant)
	3.2 (intermediate resistance)

**Breakpoints**

*Streptococcus pneumoniae*: S ≤ 2 mcg/mL; I = 4 mcg/mL; R ≥ 8 mcg/mL.

**Note:** Because amoxycillin has a 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.

**Susceptibility Tests**

Dilution or 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 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.

## 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 judgment will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results.

### **Skin and Skin Structure:**

Staphylococcus, non-penicillinase producing; Streptococcus; *E. coli* (see **Microbiology**).

### **Respiratory (Acute and Chronic):**

*H. influenzae*; Streptococcus; *Strep. pneumoniae*; Staphylococcus, non-penicillinase producing; *E. coli* (see **Microbiology**).

### **Genitourinary Tract (Complicated and Uncomplicated, Acute and Chronic):**

*E. coli* (see **Microbiology**), *P. mirabilis* and *S. faecalis*.

### **Gonorrhoea:**

*N. gonorrhoeae* (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 reactions (anaphylaxis) 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 amoxycillin 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.

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.

### **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.

*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.*

### **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, 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 infant will be necessary.

### **Use in Lactation**

Ampicillin class antibiotics are excreted in breast milk; therefore, caution should be exercised when amoxycillin is administered to a nursing woman.

### **Impaired Renal Function**

Dosage should be adjusted in patients with renal impairment (see **DOSAGE AND ADMINISTRATION**).

### **Interactions with Other Medicines**

Probenecid decreases the renal tubular secretion of amoxycillin. Concurrent use with amoxycillin 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 antibiotics, amoxycillin may affect the gut flora, leading to lower oestrogen re-absorption and reduced efficacy of combined oral contraceptives.

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

### **Effect 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 Tes-Tape) 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.

## 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 has 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 rash, pruritus and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous, exfoliative dermatitis and acute generalized exanthematous pustulosis (AGEP) have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and interstitial nephritis 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 been noted occasionally 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. Prolongations of bleeding time and prothrombin time have also been reported rarely.

### CNS Effects

CNS effects have been seen rarely. These 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 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 and children (over 20 kg): 250 mg every eight hours.

Children (under 20 kg): 20 mg/kg/day in equally divided doses every eight 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 eight hours for children may be needed.

### **Lower Respiratory Tract Infections**

Adults: 500 mg every eight hours.

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

### **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 four months.

### **Acute Uncomplicated Lower Urinary Tract Infections in Non-Pregnant Adult Females**

Adults: 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 to be calculated greater than that recommended for adults. Children weighing more than 20 kg should be dosed according to the adult recommendations.

### **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 dosage.

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

### **Chronic Urinary Tract Infections**

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.

### **Duration of Treatment**

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 ten days treatment for any infection caused by haemolytic Streptococci, to prevent the occurrence of acute rheumatic fever or glomerulonephritis.

**Prophylaxis of Endocarditis:** (see Table 1 – last page).

## **OVERDOSAGE**

### **Symptoms**

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident.

### **Treatment**

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.

**Contact the Poison Information Centre on 13 11 26 (Australia) for advice on the management of overdose.**

## **PRESENTATION AND STORAGE CONDITIONS**

### **Apo-Amoxycillin 250 mg Capsules**

Opaque, yellow, hard gelatin capsules (No.2 size) imprinted with “250” in black.  
20 capsules per pack.  
AUST R 142491

### **Apo-Amoxycillin 500 mg Capsules**

Brown/yellow, opaque, hard gelatin capsules, size no. 0 (length approx. 21.5mm, diameter approx 7.5mm) imprinted with “500” in black.  
20 capsules per pack.  
AUST R 142538

Apo-Amoxycillin 250 mg and 500 mg capsules are intended for oral administration. Each capsule contains 250 mg or 500 mg, amoxycillin trihydrate.

In addition, each capsule contains the following inactive ingredients: magnesium stearate, microcrystalline cellulose, gelatin, sodium lauryl sulphate, colloidal anhydrous silica, croscarmellose sodium, sunset yellow FCF, quinoline yellow, titanium dioxide, methyl hydroxybenzoate, propyl hydroxybenzoate, shellac, black iron oxide, carmoisine (500 mg capsules) and brilliant blue FCF (500 mg capsules)

Store below 25°C, protect from moisture.

## **NAME AND ADDRESS OF THE SPONSOR**

Apotex Pty Ltd  
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North Ryde NSW 2113  
Australia

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## **POISON SCHEDULE OF THE MEDICINE**

S4: Prescription Only Medicine.

**Date of TGA approval:** 20 February 2008

**Date of most recent amendment:** 23 July 2008



TABLE 1

## Prophylaxis of Endocarditis (based on the recommendations of the British Society for Antimicrobial Chemotherapy)

Condition		Adults' Dosage (including elderly)	Children's Dosage
<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>	Patients not having general anaesthetic.	<p>3 g Amoxycillin orally, 1 hour before procedure. A second dose may be given 6 hours later if considered necessary.</p> <p>Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin.</p>	<p>Under 10 years: Half adult dose.</p> <p>Under 5 years: Quarter adult dose.</p> <p>Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin.</p>
	Patients having general anaesthetic; oral antibiotics are not appropriate.	<p>1 g Amoxycillin IM immediately before induction, with 500 mg orally, 6 hours later.</p> <p>Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin.</p>	<p>Under 10 years: Half adult dose.</p> <p>Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin.</p>
<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: 1 g Amoxycillin IM with 120 mg gentamicin IM, immediately prior to anaesthesia (if given) or 15 minutes prior to dental procedure.</p> <p>Followed by (6 hours later): 500 mg Amoxycillin orally.</p>	<p>Under 10 years: The amoxycillin doses should be half the adult dose; the dose of gentamicin should be 2mg/kg.</p>
<p><i>Genitourinary surgery or instrumentation.</i> Prophylaxis for patients who have no urinary tract infection and who are to have genitourinary surgery or instrumentation under general anaesthesia.</p> <p><i>Obstetric and gynaecological procedures</i> <i>Gastrointestinal procedures</i> Routine prophylaxis is recommended only for patients with prosthetic heart valves.</p>		<p>Initially: 1 g Amoxycillin IM with 120 mg gentamicin IM, immediately before induction.</p> <p>Followed by (6 hours later): 500 mg Amoxycillin orally or IM according to clinical condition.</p>	<p>Under 10 years: The amoxycillin doses should be half the adult dose; the dose of gentamicin should be 2mg/kg</p>
<p><i>Surgery or Instrumentation of the Upper Respiratory Tract.</i></p>	Patients other than those with prosthetic heart valves.	<p>1 g Amoxycillin IM immediately before induction.</p> <p>Followed by (6 hours later): 500 mg Amoxycillin IM.</p>	<p>Under 10 years: Half adult dose.</p>
	Patients with prosthetic heart valves.	<p>Initially: 1 g Amoxycillin IM with 120 mg gentamicin IM, immediately before induction.</p> <p>Followed by (6 hours later): 500 mg Amoxycillin IM.</p>	<p>Under 10 years: The amoxycillin doses should be half the adult doses; the dose of gentamicin should be 2 mg/kg.</p>