1000000
0053832

Amoxil™

Amoxicillin

Qualitative and Quantitative Composition

Amoxil Vials for Injection 250 mg contain 250 mg amoxicillin.
Amoxil Vials for Injection 500 mg contain 500 mg amoxicillin
The amoxicillin is present as the sodium salt in Amoxil injections
Each Amoxil Injection 250 mg vial contains approximately **0.8 mmol** of Sodium.
Each Amoxil Injection 500 mg vial contains approximately **1.7 mmol** of Sodium.
Not all presentations are available in every market.

Pharmaceutical Form

Amoxil Vials: vials containing sterile powder for reconstitution.

Indications

Amoxil is a broad spectrum antibiotic indicated for the treatment of commonly occurring bacterial infections such as:
Upper respiratory tract infections e.g. ear, nose and throat infections, otitis media, Lower respiratory tract infections e.g. acute and chronic bronchitis, chronic bronchial sepsis, lobar and bronchopneumonia, Gastrointestinal tract infections e.g. typhoid and paratyphoid fever, Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy, septic abortion, puerperal sepsis, Skin and soft tissue infections, Intra-abdominal sepsis, Gonorrhoea, Septicaemia, Bacterial endocarditis, Peritonitis.
In children with urinary tract infection the need for investigation should be considered.
Prophylaxis of endocarditis: Amoxil may be used for the prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis.
Strains of the following organisms are generally sensitive to the bactericidal action of Amoxil in vitro:
Gram-positive: S*treptococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans,* (penicillin-sensitive) *Staphylococcus aureus, Corynebacterium* species, *Bacillus anthracis, Listeria monocytogenes, Clostridium* species.
Gram-negative: *Haemophilus influenzae, Escherichia coli, Proteus mirabilis, Salmonella* species, *Shigella* species, *Bordetella pertussis, Brucella* species, *Neisseria gonorrhoeae, Neisseria meningitides, Vibrio cholerae, Pasteurella septica*

Posology and Method of Administration

Treatment of infection:
Adult dosage (including elderly patients)
500 mg IM eight hourly (or more frequently if necessary) in moderate infections. (This dose may be given by slow IV injection if more convenient.)
1 g IV six hourly in severe infections.
Children's dosage (up to 10 years of age):
50-100 mg/kg body weight a day, in divided doses.
Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.
Patients with renal impairment
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.

Prophylaxis of endocarditis:

CONDITION		ADULTS' DOSAGE (INCLUDING ELDERLY)	CHILDREN'S DOSAGE	NOTES
Dental procedures: prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues and who have not received a penicillin in the previous month. (N.B. Patients with prosthetic heart valves should be referred to hospital - see below).	Patient not having general anaesthetic.	3 g 'Amoxil' orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary.	Under 10: half adult dose. Under 5: quarter adult dose.	Note 1. If prophylaxis with 'Amoxil' is given twice within one month, emergence of resistant streptococci is unlikely to be a problem. Alternative antibiotics are recommended if more frequent prophylaxis is required, or if the patient has received a course of treatment with a penicillin during the previous month. Note 2: To minimise pain on injection, 'Amoxil' may be given as two injections of 500 mg dissolved in sterile 1% lidocaine solution (see *Administration*).
	Patient having general anaesthetic: if oral antibiotics considered to be appropriate.	Initially 3 g 'Amoxil' orally 4 hours prior to anaesthesia, followed by 3 g orally (or 1 g IV or IM if oral dose not tolerated) as soon as possible after the operation.		
	Patient having general anaesthetic: if oral antibiotics not appropriate.	1 g 'Amoxil' IV or IM immediately before induction; with 500 mg orally, 6 hours later.		
Dental procedures: patients for whom referral to hospital is recommended: a) Patients to be given a general anaesthetic who have been given a penicillin in the previous month. b) Patients to be given a general anaesthetic who have a prosthetic heart valve. c) Patients who have had one or more attacks of endocarditis.		Initially: 1 g 'Amoxil' IV or IM with 120 mg gentamicin IV or IM immediately prior to anaesthesia (if given) or 15 minutes prior to dental procedure. Followed by (6 hours later): 500 mg 'Amoxil' orally.	Under 10: the doses of 'Amoxil' should be half the adult dose; the dose of gentamicin should be 2 mg/kg. Under 5: the doses of 'Amoxil' should be quarter the adult dose; the dose of gentamicin should be 2 mg/kg.	See Note 2. Note 3. 'Amoxil' and gentamicin should not be mixed in the same syringe. Note 4. Please consult the appropriate data sheet for full prescribing information on gentamicin.
Genitourinary Surgery or Instrumentation: prophylaxis for patients who have no urinary tract infection and who are to have genito-urinary surgery or instrumentation under general anaesthesia. In the case of *Obstetric and Gynaecological Procedures* and *Gastrointestinal Procedures* – routine prophylaxis is recommended only for patients with prosthetic heart valves.		Initially: 1 g 'Amoxil' IV or IM with 120 mg gentamicin IV or IM, immediately before induction. Followed by (6 hours later): 500 mg 'Amoxil' orally or IV or IM according to clinical condition.		See Notes 2, 3 and 4 above.
Surgery or Instrumentation of the Upper Respiratory Tract	Patients other than those with prosthetic heart valves.	1 g 'Amoxil' IV or IM immediately before induction; 500 mg 'Amoxil' IV or IM 6 hours later.	Under 10: half adult dose. Under 5: quarter adult dose.	See Note 2 above. Note 5. The second dose of 'Amoxil' may be administered orally as 'Amoxil' Syrup SF/DF.
	Patients with prosthetic heart valves.	Initially: 1 g 'Amoxil' IV or IM with 120 mg gentamicin IV or IM, immediately before induction; followed by (6 hours later) 500 mg 'Amoxil' IV or IM.	Under 10: the dose of 'Amoxil' should be half the adult dose; the gentamicin dose should be 2 mg/kg. Under 5: the dose of 'Amoxil' should be quarter the adult dose; the dose of gentamicin should be 2 mg/kg.	See Notes 2, 3, 4 and 5 above.

Administration: Intravenous Injection, Intravenous Infusion, Intramuscular.

Contraindications

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

Warnings and Precautions

Before initiating therapy with Amoxil, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. Amoxicillin 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 occasionally result in overgrowth of non-susceptible organisms. Dosage should be adjusted in patients with renal impairment. When prepared for intramuscular or direct intravenous injection, Amoxil should be administered immediately after reconstitution. The stability of Amoxil in various infusion fluids varies. Lignocaine or benzyl alcohol may be used only when administering amoxicillin by the intramuscular route. If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the 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.

Interactions

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with Amoxil may result in increased and prolonged blood levels of amoxicillin. In common with other antibiotics, Amoxil may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.

Pregnancy and Lactation

Amoxil may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment. Amoxil may be administered during the period of lactation. With the exception of the risk of sensitisation associated with the excretion of trace quantities of amoxicillin in breast milk, there are no known detrimental effects for the infant.

Adverse Reactions

Blood and lymphatic system disorders: Reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia, prolongation of bleeding time and prothrombin time
Immune system disorders: As with other antibiotics, severe allergic reactions, including angioneurotic oedema, anaphylaxis, serum sickness and hypersensitivity vasculitis. If a hypersensitivity reaction is reported, the treatment must be discontinued.
Nervous system disorders: Hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.
Infections and Infestations: Mucocutaneous candidiasis
Gastrointestinal disorders: Diarrhoea, nausea, vomiting and antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis).
Hepato-biliary disorders: Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT. The significance of a rise in AST and/or ALT is unclear.
Skin and subcutaneous tissue disorders: Skin rash, urticaria, pruritus, skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP).
Renal and Urinary tract disorders: Interstitial nephritis, crystalluria

Overdosage

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water/electrolyte imbalance should be treated symptomatically. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. Amoxicillin has been reported to precipitate in bladder catheters after intravenous administration of large doses. A regular check of patency should be maintained. Amoxicillin can be removed from the circulation by haemodialysis.

Incompatibilities

Amoxil should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates, or with intravenous lipid emulsions. If Amoxil is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions. Amoxil solutions should not be mixed with infusions containing glucose, dextran or bicarbonate.

Shelf Life

The expiry date is indicated on the outer packaging

Special Precautions for Storage

Store in a dry place, below 25°C.
When prepared for intramuscular or direct intravenous injection, Amoxil should be administered immediately after reconstitution. The stability of Amoxil in various infusion fluids is dependent upon the concentration and temperature.

Instructions for Use/Handling

Intravenous Injection:
Dissolve 250 mg in 5.0 ml Water for Injections BP (Final volume=5.2 ml).
Dissolve 500 mg in 10 ml Water for Injections BP (Final volume=10.4 ml).
Amoxil injection, suitably diluted, may be injected directly into a vein or the infusion line over a period of 3-4 minutes.
Intravenous Infusion:
Solutions may be prepared as described for intravenous injections and then added to an intravenous solution in a minibag or in-line burette and administered over a period of half to one hour. Alternatively, using a suitable reconstitution device, the appropriate volume of intravenous fluid may be transferred from the infusion bag into the vial and then drawn back into the bag after dissolution.
Intramuscular:
250 mg: Add 1.5 ml Water for Injections BP † and shake vigorously (Final volume=1.7 ml).
500 mg: Add 2.5 ml Water for Injections BP † and shake vigorously (Final volume=2.9 ml).
† If pain is experienced on intramuscular injection, a sterile 1% solution of lidocaine hydrochloride or 0.5% solution of procaine hydrochloride may be used in place of Water for Injections.
A transient pink colouration or slight opalescence may appear during reconstitution. Reconstituted solutions are normally a pale straw colour.

INSTRUCTIONS TO THE PATIENT

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The Doctor and the Pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting the doctor.

Keep medicament out of the reach of children

Council of Arab Health Minister
Union of Arab Pharmacists

Manufactured by: SmithKline Beecham plc*, Worthing, UK
*Member of the GlaxoSmithKline group of companies

Version number: GDS21, **Date of issue:** 13 November 2007

GlaxoSmithKline