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Amoxil™

Amoxicillin

Qualitative and Quantitative Composition
Amoxil Syrup Sucrose Free/Dye Free 125 mg contains 125 mg amoxicillin per 5 ml dose.
Amoxil Syrup Forte Sucrose Free/Dye Free 250 mg contains 250 mg amoxicillin per 5 ml dose.
The amoxicillin is present as the trihydrate.

Pharmaceutical Form
Amoxil Syrup and Syrup Forte: citrus-flavoured sucrose-free/dye-free syrups in a sorbitol base. Presented as powder in bottles for preparing 100 ml. Not all presentations are available in every market.

Indications
Treatment of Infection: 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, Dental abscess (as an adjunct to surgical management), Osteomyelitis. 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.
The wide range of organisms sensitive to the bactericidal action of Amoxil include:
Gram-positive: *Streptococcus 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):
Oral:
Standard adult dosage: 250 mg three times daily, increasing to 500 mg three times daily for more severe infections.
High dosage therapy (maximum recommended oral dosage 6 g daily in divided doses): A dosage of 3 g twice daily is recommended in appropriate cases for the treatment of severe or recurrent purulent infection of the respiratory tract.
Short course therapy: Simple acute urinary tract infection: two 3 g doses with 10-12 hours between the doses. Dental abscess: two 3 g doses with 8 hours between the doses. Gonorrhoea: single 3 g dose.
Injectable: 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):
Oral:
Standard children's dosage: 125 mg three times daily, increasing to 250 mg three times daily for more severe infections. Amoxil Paediatric Suspension is recommended for children under six months of age. In severe or recurrent acute otitis media, especially where compliance may be a problem, 750 mg twice a day for two days may be used as an alternative course of treatment in children aged 3 to 10 years.
Injectable: 50-100 mg/kg body weight a day, in divided doses.
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 according to the following scheme:
Adults and Children over 40 kg:
Mild impairment (creatinine clearance > 30ml/min): No change in dosage
Moderate impairment (creatinine clearance 10-30 ml/min): 500 mg b.i.d. maximum
Severe impairment (creatinine clearance <10 ml/min): 500 mg/day maximum
Children under 40 kg:
Mild impairment (creatinine clearance > 30ml/min): No change in dosage
Moderate impairment (creatinine clearance 10-30 ml/min): 15 mg/kg b.i.d.
Severe impairment (creatinine clearance <10 ml/min): 15 mg/kg o.d.
Patients receiving peritoneal dialysis: Dosing as for patients with severe renal impairment (creatinine clearance <10 ml/min) amoxicillin is not removed by peritoneal dialysis
Patients receiving haemodialysis: Dosing as for patients with severe renal impairment (creatinine clearance <10 ml/min). Amoxicillin is removed from the circulation by haemodialysis. Therefore, one additional dose (500 mg for adults or 15 mg/kg for children under 40 kg) may be administered during dialysis and at the end of each dialysis. 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.
Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.

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% lignocaine 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: Oral

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.
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.
Amoxil Syrup 125 mg and Amoxil Syrup Forte 250 mg contain sodium benzoate

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, antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis) and Black hairy tongue. Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.
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 can be removed from the circulation by haemodialysis.

List of Excipients
The powder contains disodium edetate, sodium benzoate (E211), saccharin sodium, silica (E551), xanthan gum (E415), peach, strawberry and lemon dry flavours and sorbitol (E420).

Shelf Life
The expiry date is indicated on the outer packaging

Special Precautions for Storage
Do not store above 25°C. Store powder in a dry place. Once reconstituted, Amoxil Syrup SF/DF should be used within 14 days. If dilution of the reconstituted SF/DF product is required, water should be used.

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

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