Amoxil™

Amoxicillin

Qualitative and Quantitative Composition (active ingredient only)
AMOXIL **Capsules 250 mg** contain 250 mg amoxicillin per capsule
AMOXIL **Capsules 500 mg** contain 500 mg amoxicillin per capsule
The amoxicillin is present as the trihydrate in *AMOXIL* oral presentations.

Pharmaceutical Form
AMOXIL **Capsules**: maroon and gold capsules overprinted
"GS JVL" (for 500 mg capsule), "GS LEX" (for 250 mg capsule).
Not all presentations are available in every market.

CLINICAL PARTICULARS

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 (non-penicillinase producing strains)
- Septicaemia
- Bacterial endocarditis
- Peritonitis
- Dental abscess (as an adjunct to surgical management)
- *Helicobacter pylori* eradication in peptic (duodenal and gastric) ulcer disease.

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 endocarditis.
Consideration should be given to official local guidance (e.g. national requirements) on the appropriate use of antibacterial agents."Susceptibility of the causative organism to the treatment should be tested (if possible), although the therapy may be initiated before the results are available.

Dosage and Administration
Treatment of Infection:
Adult dosage (including elderly patients):
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.
Helicobacter eradication in peptic (duodenal and gastric) ulcer disease:
AMOXIL is recommended at a dose of twice daily in association with a proton pump inhibitor and antimicrobial agents as detailed below:
Omeprazole 40 mg daily, Amoxicillin 1 Gm BID, Clarithromycin 500 mg BID x7 days
or
Omeprazole 40 mg daily, Amoxicillin 750 mg-1 Gm BID, Metronidazole 400 mg TID x 7 days
Renal impairment:
Glomerular filtration rate >30ml/min No adjustment necessary.
Glomerular filtration rate 10-30ml/min: Amoxicillin. max. 500mg b.d
Glomerular filtration rate <10ml/min: Amoxicillin. max. 500mg/day
Children's dosage: (up to 10 years of age):
Standard children's dosage: 125 mg three times daily, increasing to 250 mg three times daily for more severe infections.
Renal impairment in children under 40 kg:
Creatinine clearance >30mL/min: No adjustment necessary.
Creatinine clearance 10-30mL/min: 15 mg/kg given b.i.d
Creatinine clearance <10mL/min: 15 mg/kg given as a single daily dose
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.
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% 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:
Treatment should be continued for 2 to 3 days following the disappearance of symptoms. It is recommended that at least 10 days treatment be given for any infection caused by beta-haemolytic streptococci in order to achieve eradication of the organism.

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

Special Warnings and Special Precautions for Use
Before initiating therapy with *AMOXIL*, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to beta lactam antibiotics (see *Contraindications*).
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 also occasionally result in overgrowth of non-susceptible organisms.
Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin 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.
Dosage should be adjusted in patients with renal impairment (see *Dosage and Administration*).
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 possiblity of amoxicillin crystalluria.
(See *Overdose*)

Interactions
Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant 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.
Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.
Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.
It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive reading are common with chemical methods.
In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

Pregnancy and Lactation
The safety of this medicinal product for use in human pregnancy has not been established by well controlled studies in pregnant women. Reproduction studies have been performed in mice and rats at doses up to ten times the human dose and these studies have revealed no evidence of impaired fertility or harm to the foetus due to amoxicillin. Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.
Amoxicillin may be given during 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 breast-fed infant.

Effects on Ability to Drive and Use Machines
Adverse effects on the ability to drive or operate machinery have not been observed.

Adverse Reactions
The following convention has been utilised for the classification of undesirable effects:- Very common (more than 1/10), common (more than 1/100, less than 1/10), uncommon (more than 1/1000, less than 1/100), rare (more than 1/10,000, less than 1/1000), very rare (less than 1/10,000).
The majority of the side-effects listed below are not unique to amoxicillin and may occur when using other penicillins.
Unless otherwise stated, the frequency of adverse events (AE's) has been derived from more than 30 years of post-marketing reports.
Blood and lymphatic system disorders
Very rare: Reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin time (See Interactions).
Immune system disorders
Very rare: As with other antibiotics, severe allergic reactions, including angioneurotic oedema, anaphylaxis (see Warnings and Precautions), serum sickness and hypersensitivity vasculitis.
If a hypersensitivity reaction is reported, the treatment must be discontinued.
(See also Skin and subcutaneous tissue disorders).
Nervous system disorders
Very rare: Hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.
Infections and Infestations
Very rare: Mucocutaneous candidiasis
Gastrointestinal disorders
Common: Diarrhoea and nausea.
Uncommon: Vomiting.
Very rare: Antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis).
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
Very rare: 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
Common: Skin rash.
Uncommon: Urticaria and pruritus.
Very rare: Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP). (See also Immune system disorders).
Renal and Urinary tract disorders
Very rare: Interstitial nephritis, crystalluria (see Overdose)
The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin.

Overdose
Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance.
Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see warnings and precautions)
Amoxicillin can be removed from the circulation by haemodialysis.

PHARMACEUTICAL PARTICULARS

List of Excipients
Each capsule contains magnesium stearate (E572) and erythrosine (E127), indigo carmine (E132), titanium dioxide (E171), yellow iron oxide (E172) and gelatin.

Shelf Life
The expiry date is indicated on the packaging.

Special Precautions for Storage
Store in a dry place.
Do not store above 30° C
AMOXIL is a trademark of the GlaxoSmithKline group of companies.
Manufactured by
SmithKline Beecham Limited*
Worthing, UK
Packed by:
Glaxo Wellcome Production*
Mayenne, France
*Member of the GlaxoSmithKline group of companies

GDS Version Number: 23
Version Date: 27 April 2009

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

GlaxoSmithKline