PRODUCT DESCRIPTION

Amoxicillin (Amoxil®) 125mg/5mL Powder for Suspension: Bottles of white powder (for reconstitution) with yellowish grains and a characteristic fruity odour. When reconstituted, a lemon-peach-strawberry flavoured suspension is formed and each 5mL contains 125mg amoxicillin.

Amoxicillin (Amoxil®) Forte 250mg/5mL Powder for Suspension: Bottles of white powder (for reconstitution) with yellowish grains and a characteristic fruity odour. When reconstituted, a lemon-peach-strawberry flavoured suspension is formed and each 5mL contains 250mg amoxicillin.

Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops): Bottles of white powder (for reconstitution) with yellowish grains and a characteristic fruity odour. When reconstituted, a lemon-peach-strawberry flavoured suspension is formed and each 1mL contains 100mg amoxicillin.

Amoxicillin (Amoxil®) 250mg Capsules: Each two-coloured capsule (yellow opaque body – red opaque cap) printed with GS LEX in white ink encapsulating a white to off white powder contains 250mg amoxicillin.

Amoxicillin (Amoxil®) 500mg Capsules: Each two-coloured capsule (yellow opaque body – red opaque cap) printed with GS JVL in white ink encapsulating a white to off white powder contains 500mg amoxicillin.

PHARMACOLOGIC PROPERTIES

Pharmacodynamics

Amoxicillin is a semi-synthetic aminopenicillin of the beta-lactam group of antibiotics. It has a broad spectrum of antibacterial activity against many Gram-positive and Gram-negative micro-organisms, acting through the inhibition of biosynthesis of cell wall muropeptide. Amoxicillin is, however, susceptible to degradation by beta lactamases and therefore the spectrum of activity does not include organisms which produce these enzymes including resistant staphylococci, and all strains of Pseudomonas, Klebsiella, and Enterobacter. It is rapidly bactericidal and possesses the safety profile of a penicillin.

The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is durable, particularly when treating severe infections.

<table>
<thead>
<tr>
<th>Commonly Susceptible Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram-positive aerobes:</td>
</tr>
<tr>
<td>Bacillus anthracis</td>
</tr>
<tr>
<td>Enterococcus faecalis*</td>
</tr>
<tr>
<td>Beta-hemolytic streptococci*</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
</tr>
<tr>
<td>Gram-negative aerobes:</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>Leptospira icterohaemorrhagiae</td>
</tr>
<tr>
<td>Treponema pallidum</td>
</tr>
<tr>
<td>Species for which acquired resistance may be a problem</td>
</tr>
<tr>
<td>Gram-negative aerobes:</td>
</tr>
<tr>
<td>Escherichia coli*</td>
</tr>
<tr>
<td>Haemophilus influenzae*</td>
</tr>
<tr>
<td>Helicobacter pylori*</td>
</tr>
<tr>
<td>Proteus mirabilis*</td>
</tr>
<tr>
<td>Salmonella spp.</td>
</tr>
<tr>
<td>Shigella spp.</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae*</td>
</tr>
<tr>
<td>Pasteurella spp.</td>
</tr>
<tr>
<td>Vibrio cholera</td>
</tr>
<tr>
<td>Gram-positive aerobes:</td>
</tr>
<tr>
<td>Coagulase negative staphylococcus*</td>
</tr>
<tr>
<td>Corynebacterium spp.</td>
</tr>
<tr>
<td>Staphylococcus aureus *</td>
</tr>
<tr>
<td>Streptococcus pneumoniae*</td>
</tr>
<tr>
<td>Viridans group streptococci*</td>
</tr>
<tr>
<td>Gram-positive anaerobes:</td>
</tr>
<tr>
<td>Clostridium spp.</td>
</tr>
<tr>
<td>Gram-negative anaerobes:</td>
</tr>
<tr>
<td>Fusobacterium spp.</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>Borrelia burgdorferi</td>
</tr>
<tr>
<td>Inherently resistant organisms</td>
</tr>
<tr>
<td>Gram-positive aerobes:</td>
</tr>
<tr>
<td>Enterococcus faecium†</td>
</tr>
</tbody>
</table>
**DOSAGE AND ADMINISTRATION**

**Adults and children over 40 kg:**

- **Standard adult dosage:** 250 mg 3 times daily, increasing to 500 mg 3 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 to 12 hours between the doses. Dental abscess: two 3 g doses with 8 hours between the doses. Gonorrhoea: single 3 g dose.

**Eradication of H. Pylori:** Amoxicillin 750 mg to 1 g twice daily in combination with a proton pump inhibitor (e.g. omeprazole, lansoprazole) and another antibiotic (e.g. clarithromycin, metronidazole) for 7 days.

**Children under 40 kg:**

- Standard children’s dosage: 125 mg 3 times daily, increasing to 250 mg 3 times daily for more severe infections.

**Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops) is recommended for children under 6 months of age.**

**Acute otitis media:** 750 mg twice a day for 2 days may be used as an alternative course of treatment.

**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 greater than 30 ml/min) – No change in dosage
    - Moderate impairment (creatinine clearance 10 to 30 ml/min) – 500 mg twice a day maximum
    - Severe impairment (creatinine clearance less than 10 ml/min) – 500 mg/day maximum

**Pharmacokinetics**

Amoxicillin is well absorbed. Oral administration, usually at convenient three times a day dosage, produces high serum levels independent of the time at which food is taken. Amoxicillin gives good penetration into bronchial secretions and high urinary concentrations of unchanged antibiotic.

Amoxicillin is not highly protein bound; approximately 18% of total plasma drug content is bound to protein. Amoxicillin diffuses readily into most body tissues and fluids, with the exception of the brain and spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins and this may apply to Amoxicillin.

The major route of elimination for Amoxicillin is via the kidney. Approximately 60 to 70% of amoxicillin is excreted unchanged in urine during the first six hours after administration of a standard dose. The elimination half-life is approximately one hour. Amoxicillin is also partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to 10 to 25% of the initial dose.

Concurrent administration of probenecid delays Amoxicillin excretion.

Small amounts of the drug are also excreted in faeces and bile.

**INDICATIONS**

Amoxicillin-clavulinate should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. Amoxicillin (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 exacerbations of chronic bronchitis, 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.
- Other infections including Borrelia (Borrelia burgdorferi) (Lyme disease) Skin and soft tissue infections.
- Biliary tract infections.
- Bone infections.
- Pelvic infections.
- Gonorrhoea (non-penicillinase producing strains).
- Septicaemia.
- Endocarditis.
- Meningitis.
- Peritonitis.
- Dental abscesses (as an adjunct to surgical management).
- Helicobacter pylori eradication in peptic (duodenal and gastric) ulcer disease.

Infections such as septicemia, endocarditis and meningitis due to susceptible organisms should be treated initially with high doses of a parenteral therapy and, where appropriate, in combination with another antibiotic. Prophylaxis of endocarditis: Amoxicillin (Amoxil®) may be used for the prevention of bacteraemia associated with procedures such as dental extraction, in patients at risk of developing endocarditis (see Dosage and Administration).

Susceptibility to Amoxicillin (Amoxil®) will vary with geography and time and local susceptibility data should be consulted where available and microbiological sampling and susceptibility testing where necessary (see Pharmacodynamics).

**Gram-negative aerobes:**

- Acinetobacter spp.
- Enterobacter spp.
- Klebsiella spp.
- Pseudomonas spp.

**Gram-negative anaerobes:**

- Bacteroides spp. (many strains of Bacteroides fragilis are resistant)

**Others:**

- Chlamydia spp.
- Mycoplasma spp.
- Legionella spp.

**Pharmacodynamics**

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**Children under 40 kg:**

- Standard children’s dosage: 125 mg 3 times daily, increasing to 250 mg 3 times daily for more severe infections.

**Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops) is recommended for children under 6 months of age.**

**Acute otitis media:** 750 mg twice a day for 2 days may be used as an alternative course of treatment.

**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 greater than 30 ml/min) – No change in dosage
- Moderate impairment (creatinine clearance 10 to 30 ml/min) – 500 mg twice a day maximum
- Severe impairment (creatinine clearance less than 10 ml/min) – 500 mg/day maximum
**Prophylaxis of endocarditis:**

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>ADULTS’ DOSAGE (INCLUDING ELDERLY)</th>
<th>CHILDREN’S DOSAGE</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>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).</strong></td>
<td>Patient not having general anaesthetic.</td>
<td>3 g Amoxicillin (Amoxil®) orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary.</td>
<td>Under 10 years: half adult dose. Under 5 years: quarter adult dose. The use of Amoxicillin (Amoxil®) 500 mg Dispersible Tablets or 750 mg Sachets SF is recommended.</td>
</tr>
<tr>
<td></td>
<td>Patient having general anaesthetic: if oral antibiotics considered to be appropriate.</td>
<td>Initially 3 g Amoxicillin (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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient having general anaesthetic: if oral antibiotics not appropriate</td>
<td>1 g Amoxicillin (Amoxil®) IV or IM immediately before induction; with 500 mg orally, 6 hours later.</td>
<td></td>
</tr>
<tr>
<td><strong>Dental procedures: patients for whom referral to hospital is recommended:</strong></td>
<td>a) Patients to be given a general anaesthetic who have been given a penicillin in the previous month.</td>
<td>Initially: 1 g Amoxicillin (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 Amoxicillin (Amoxil®) orally.</td>
<td>Under 10 years: the doses of Amoxicillin (Amoxil®) should be half the adult dose; the dose of gentamicin should be 2 mg/kg. Under 5 years: the doses of Amoxicillin (Amoxil®) should be quarter the adult dose; the dose of gentamicin should be 2 mg/kg.</td>
</tr>
<tr>
<td></td>
<td>b) Patients to be given a general anaesthetic who have a prosthetic heart valve.</td>
<td></td>
<td>See Note 2.</td>
</tr>
<tr>
<td></td>
<td>c) Patients who have had one or more attacks of endocarditis.</td>
<td></td>
<td>Note 3. Amoxicillin (Amoxil®) and gentamicin should not be mixed in the same syringe.</td>
</tr>
<tr>
<td><strong>Genitourinary Surgery or Instrumentation:</strong> prophylaxis for patients who have no urinary tract infection and who are to have genitourinary surgery or instrumentation under general anaesthesia.</td>
<td></td>
<td></td>
<td>Note 4. Please consult the appropriate data sheet for full prescribing information on gentamicin</td>
</tr>
<tr>
<td><strong>Obstetric and Gynaecological Procedures and Gastrointestinal Procedures:</strong> routine prophylaxis is recommended only for patients with prosthetic heart valves.</td>
<td>Initially: 1 g Amoxicillin (Amoxil®) IV or IM with 120 mg gentamicin IV or IM immediately prior to induction. Followed by (6 hours later): 500 mg Amoxicillin (Amoxil®) orally or IV or IM according to clinical condition.</td>
<td>Under 10 years: the doses of Amoxicillin (Amoxil®) should be half the adult dose; the dose of gentamicin should be 2 mg/kg. Under 5 years: the doses of Amoxicillin (Amoxil®) should be quarter the adult dose; the dose of gentamicin should be 2 mg/kg.</td>
<td>See Notes 2, 3 and 4 above.</td>
</tr>
</tbody>
</table>
Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.

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

**WARNINGS AND PRECAUTIONS**
Before initiating therapy with Amoxicillin (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). If an allergic reaction occurs, Amoxicillin (Amoxil®) should be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, may also be required. 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. Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhea during or after antibiotic use. If prolonged or significant diarrhea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

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 possibility of Amoxicillin crystalluria (see Overdose).

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving Amoxicillin (Amoxil®) 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.

Amoxicillin (Amoxil®) 125mg/5mL Powder for Suspension, Amoxicillin (Amoxil® Forte) 250mg/5mL Powder for Suspension and Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops):
- contain sodium benzoate which is a mild irritant to the skin, eyes, and mucus membrane. It may increase the risk of jaundice in newborn babies.
- may contain aspartame which is a source of phenylalanine and so should be used with caution in patients with phenylketonuria.
- may contain sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

**DRUG INTERACTIONS**
Probenecid decreases the renal tubular secretion of Amoxicillin. Concomitant use with Amoxicillin (Amoxil®) may result in increased and prolonged blood levels of Amoxicillin. In common with other antibiotics, Amoxicillin (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. It is recommended that when testing for the presence of glucose in urine during Amoxicillin (Amoxil®) treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of Amoxicillin, false positive readings 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 (Amoxil®).
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 of up to 10 times the human dose and these studies have revealed no evidence of impaired fertility or harm to the foetus due to Amoxicillin. Amoxicillin (Amoxil®) may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Amoxicillin (Amoxil®) 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.

ADVERSE EFFECTS

The following convention has been utilised for the classification of undesirable effects: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

The majority of the side-effects listed below are not unique to Amoxicillin (Amoxil®) and may occur when using other penicillins. Unless otherwise stated, the frequency of adverse events (AEs) 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.

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 pseudomembranous colitis and haemorrhagic colitis see Warnings and Precautions), 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 (for suspension formulations only).

Hepatobiliary disorders

Very rare: Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT is unclear.

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.

OVERDOSAGE AND TREATMENT

Gastrointestinal effects such as nausea, vomiting and diarrhea 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 (see Warnings and Precautions). Amoxicillin (Amoxil®) can be removed from the circulation by haemodialysis.

STORAGE CONDITIONS

All presentations should be stored in a dry place, at temperatures not exceeding 25°C. The reconstituted Amoxicillin (Amoxil®) 125mg/5mL Powder for Suspension, (Amoxil® Forte) 250mg/5mL Powder for Suspension and 100mg/mL Powder for Suspension (Oral Drops) will retain its potency for 7 days when stored at refrigerated temperatures (between 2-8°C).

INSTRUCTIONS FOR USE/HANDLING

Directions for making up the suspension (reconstitution):

- Check cap seal is intact before use.
- Invert and shake bottle to loosen powder.
- Fill the bottle with water to just below the mark on bottle label.
- Invert and shake well, then top up with water to the mark. Invert and shake again.
- Shake well before taking each dose.

Amoxicillin (Amoxil®) 125mg/5mL Powder for Suspension and Amoxicillin (Amoxil® Forte) 250mg/5mL Powder for Suspension: To make up to 60mL reconstituted suspension, loosen the powder by shaking. Add water up to 2/3 of level indicated by the
mark on the label. Shake well for 1 minute and then let it stand for 1 minute. Then add water up to the mark on the label and shake well for 30 seconds. Shake well before use.

Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops): To make up to 20mL reconstituted suspension, loosen the powder by shaking. Add water up to 2/3 of level indicated by the mark on the label. Shake well for 1 minute and then let it stand for 1 minute. Then add water up to the mark on the label and shake well for 30 seconds. Shake well before use.

**AVAILABILITY**
Amoxicillin (Amoxil®) 250mg Capsules: 10 capsules per blister (Box of 100’s)
Amoxicillin (Amoxil®) 500mg Capsules: 10 capsules per blister (Box of 100’s)
Amoxicillin (Amoxil® Forte) 250mg/5mL Powder for Suspension: Packaging of 60mL in a clear glass bottle (Box of 1’s)
Amoxicillin (Amoxil®) 125mg/5mL Powder for Suspension: Packaging of 60mL in a clear glass bottle (Box of 1’s)
Amoxicillin (Amoxil®) 100mg/mL Powder for Suspension (Oral Drops): Packaging of 20mL in a clear glass bottle (Box of 1’s)

**CAUTION**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep all medicines out of reach of children.

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