

AMOXICILLIN ORAL SUSPENSION BP 125 mg/5 ml Pulmoxyl 125 Dry syrup

COMPOSITION:

Each 5ml of the reconstituted suspension contains:
Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg

DESCRIPTION:

An off- white, free flowing granular powder

Appearance of the reconstituted suspension: Orange coloured suspension having characteristic odour.

PHARMACOLOGICAL ACTION:

Amoxicillin is semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.

Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.

INDICATIONS:

Amoxicillin should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.

Amoxicillin 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

Skin and soft tissue infections.

Biliary tract infections

Bone infections

Pelvic infections

Gonorrhoea (non-penicillinase producing strains)

Septicaemia

Endocarditis

Meningitis

Peritonitis

Dental abscess (as an adjunct to surgical management)

Helicobacter pylori eradication in peptic (duodenal and gastric) ulcer disease

Infections such as septicaemia, 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 may be used for the prevention of bacteraemia associated with procedures such as dental extraction, in patients at risk of developing endocarditis.

Susceptibility to amoxicillin will vary with geography and time and local susceptibility data should be consulted where available and microbiological sampling and susceptibility testing performed where necessary.

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

PRECAUTIONS AND WARNINGS:

Before initiating therapy with Amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse 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 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 diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea 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 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 Paediatric Suspension contains sodium benzoate which is a mild irritant to the skin, eyes and mucus membrane. It may increase the risk of jaundice in new-born babies.

Effects on Ability to Drive and Use Machines

Adverse effects on the ability to drive or operate machinery have not been observed

USAGE IN PREGNANCY:

Pregnancy: 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 may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Lactation: 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.

ADVERSE REACTIONS:

The following convention has been utilised for the classification of undesirable effects: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$). The majority of the side-effects listed below are not unique to Amoxicillin 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.

Infections and infestations	
Very rare	Mucocutaneous candidiasis
Blood and lymphatic system disorders:	
Very rare	Reversible leucopenia (including severe neutropenia and agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin time
Immune system disorders	
Very rare	Severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness and hypersensitivity Vasculitis
Not Known	Jarisch-Herxheimer reaction
Nervous system disorders	
Very rare	Hyperkinesia, dizziness and convulsions
Gastrointestinal disorders	
<i>Clinical trial data</i>	
*Common	Diarrhoea and nausea
*Uncommon	Vomiting
<i>Post-marketing data</i>	
Very rare	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) Black hairy tongue Superficial tooth discolouration
Hepatobiliary disorders	
Very rare	Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT.
Skin and subcutaneous tissue disorders	
<i>Clinical Trial Data</i>	
*Common:	Skin rash
*Uncommon:	Urticaria and pruritus
<i>Post-marketing data</i>	
Very rare	Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Renal and urinary tract disorders	
Very rare	Interstitial nephritis Crystalluria
Nervous system disorders Very rare	Aseptic meningitis

DRUG INTERACTIONS/COMPATIBILITES:

Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with Amoxicillin may result in increased and prolonged blood levels of amoxicillin.

In common with other antibiotics, Amoxicillin 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 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.

DOSAGE:**Adult dosage (including elderly patients):**

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.

Helicobacter eradication in peptic (duodenal and gastric) ulcer disease:

Amoxicillin 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 g twice a day, Clarithromycin 500 mg twice a day for 7 days.

or

Omeprazole 40 mg daily, Amoxicillin 750 mg to 1 g twice a day, Metronidazole 400 mg 3 times a day for 7 days.

Children's dosage (up to 10 years of age):

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

Amoxicillin Paediatric Suspension is recommended for children under 6 months of age.

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

Children under 40 kg:

Mild impairment (creatinine clearance greater than 30 mL/min)

- No change in dosage

Moderate impairment (creatinine clearance 10 to 30 mL/min)

- 15 mg/kg twice a day (maximum 500 mg/twice daily)

Severe impairment (creatinine clearance less than 10 mL/min)

- 15 mg/kg once a day (maximum 500 mg)

Patients receiving peritoneal dialysis:

Dosing as for patients with severe renal impairment (creatinine clearance less than 10 mL/min). Amoxicillin is not removed by peritoneal dialysis.

Patients receiving haemodialysis:

Dosing as for patients with severe renal impairment (creatinine clearance less than 10 mL/min)

Amoxicillin is removed from the circulation by haemodialysis. Therefore, 1 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.

Prophylaxis of endocarditis: see table below.

Prophylaxis of endocarditis:

Consideration should be given to official guidelines and/or hospital and dental formularies.

Condition		Adults and children over 40kg	Children under 40kg
Dental procedures: In patients with the highest risk of infective endocarditis that require manipulation of the gingival or Periapical region of the teeth, or perforation of the oral mucosa.	Patients not having general anaesthetic.	2 g as a single oral dose 30 to 60 minutes before procedure	50 mg/kg as a single oral dose 30 to 60 minutes before procedure.

Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, and particularly for the urgent treatment of severe infection.

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.

PRESENTATION: 100ml glass bottle with measuring cup.

STORAGE: Store below 25°C.

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