PENAMOX®

Amoxicillin (as trihydrate)

INDICATIONS

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

Strains of the following organisms are generally sensitive to the bactericidal action of Penamox in vitro:

Gram-positive

Aerobes: Streptococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, penicillin-sensitive Staphylococcus aureus, Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.

Anaerobes: Clostridium species.

Gram-negative

Aerobes: Haemophilus influenzae, Escherichia coli, Proteus mirabilis, Salmonella species, Shigella species, Bordetella pertussis, Brucella species, Neisseria gonorrhoeae, Neisseria meningitidis, Pasteurella septica, Vibrio cholerae, Helicobacter pylori.

Amoxicillin is susceptible to degradation by beta-lactamases and therefore the spectrum of activity of Penamox does not include organisms which produce these enzymes, including resistant staphylococci and all strains of *Pseudomonas, Klebsiella* and *Enterobacter.*

DOSAGE AND ADMINISTRATION

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 urinary 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:

Penamox 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

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.

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 according to the following schemes:

Adults and Children over 40 kg

Mild impairment (creatinine clearance > 30 ml/min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severe impairment (creatinine clearance <10 ml/min)
No change in dosage	500 mg b.i.d. maximum	500 mg/day maximum

Children under 40 kg

Mild impairment (creatinine clearance > 30 ml/min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severe impairment (creatinine clearance <10 ml/min)
No change in dosage	15 mg/kg b.i.d	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.

Prophylaxis of endocarditis:

Dental procedures: prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues and who have not received penicillin in the previous month

- *Patients not having general anaesthetic:*

Adults: 3 g Penamox orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary.

Children: under 10: half adult dose, under 5: quarter adult dose.

- *Patients having general anaesthetic: if oral antibiotics considered to be appropriate:*

Adults: initially 3 g Penamox orally 4 hours prior to anesthesia, followed by 3 g orally as soon as possible after the operation.

Children: under 10: half adult dose, under 5: quarter adult dose.

CONTRAINDICATIONS

Penamox is a penicillin and should not be given to penicillin-hypersensitive patients. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. cephalosporins.

WARNINGS AND PRECAUTIONS

Before initiating therapy with Penamox, 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.

Erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving amoxicillin.

Prolonged use may also 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.

SIDE EFFECTS

Side-effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature.

Hyper sensitivity reactions: If any hypersensitivity occurs, the treatment should be discontinued. Skin rash, pruritis and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis(Lyell's syndrome), bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP) have been reported.

As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, and hypersensitivity vasculitis have been reported rarely.

Interstitial nephritis can occur rarely.

Renal and urinary tract disorders: Very rare: crystalluria

Gastrointestinal reactions: Effects include nausea, vomiting and diarrhea.

Intestinal candidiasis and antibiotic associated colitis (including pseudo-membranous colitis sand haemorrhagic colitis) has been reported rarely.

Hepatic effects: A moderate rise in AST and/or ALT has been occasionally noted but the significance of this is unclear. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Haematological effects: As with other beta-lactams, reversible leucopenia, (including severe neutropenia or agranulocytosis) reversible thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of bleeding time and prothrombin time have also been reported rarely.

CNS effects: CNS effects have been seen rarely. They include hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Miscellaneous: Superficial tooth discolouration has been reported very rarely in children. It can usually be removed by brushing.

Pregnancy and Lactation

Use In pregnancy

Animal studies with amoxicillin have shown no teratogenic effects. Amoxicillin has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Penamox may be considered appropriate when the potential benefits outweigh the potential risks associated with treatment.

Use In 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.

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 Penamox may result in increased and prolonged blood levels of amoxicillin.

In common with other broad spectrum antibiotics, Penamox may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

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 readings are common with chemical methods.

OVERDOSAGE

Problems of overdosage with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treatedsymptomatically with attention to the water/electrolyte balance.

Amoxicillin crystalluria has been observed.

Amoxicillin can be removed from the circulation by hemodialysis.

STORAGE

Capsules: Store below 30°C.

Tablets: Store between 15-25°C.

Suspension: Store the powder in a dry place below 30°C, away from light. After reconstitution keep in refrigerator and use within seven days.

PRESENTATIONS

Capsules

PENAMOX 250 mg: Amoxicillin (as trihydrate) USP 250 mg/capsule

Excipients: croscarmellose sodium, colloidal silicon dioxide, magnesium stearate.

PENAMOX 500 mg: Amoxicillin (as trihydrate) USP 500 mg/capsule

Excipients: croscarmellose sodium, magnesium Stearate.

Tablets

PENAMOX 1 g: Amoxicillin (as trihydrate) USP 1 g/tablet

Excipients: povidone, croscarmellose sodium, magnesium stearate, polyethylene glycol, simethicone emulsion, methacrylic acid copolymer, FD&C yellow no.6 lake, hydroxypropyl methyl allulose, purified talc, titanium dioxide.

Suspension*

PENAMOX 125 mg/5 ml: Amoxicillin (as trihydrate) USP 125 mg

Excipients: xanthan gus, methyl paraben, propyl paraben, povidone, tutti frutti powder flavor, trisodiumitrate, sodium saccharin, sucrose.

PENAMOX 250 mg/5 ml: Amoxicillin (as trihydrate) USP 250 mg

Excipients: xanthan gummethyl paraben, propyl paraben, povidone K30, trisodium citrate, orange powder flavor, sodium saccharin, sugar.

PENAMOX 500 mg/5 ml: Amoxicillin (as trihydrate) USP 500 mg

Excipients: colloidal silicondioxide, xanthan gum, hypromellose, trisodium citrate DiH2, FD&C red no.3 dye,tti frutti powder flavor, sucrose, sodium benzoate.

* Per 5 ml (after reconstitution)

Council of Arab Heath Ministers, Union of Arab Pharmacists

TH IS is A MEDICAMENT

- A medicament is a project which affects your health, and its consumption contrary instructions is dangerous.
- Follow the doctor's prcription strictly, the method of use and the instructions of the phrsacist who sold the medicament.
- The doctor and the prmacist 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 your doctor.

HIKMA Pharmaceuticals,
Amman-Jordan

Keep medicament out of the reach of children

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