**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.
- Billiary 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:** 250mg three times daily, increasing to 500mg three times daily for more severe infections.

**High dosage therapy (maximum recommended oral dosage 6g daily in divided doses):** A dosage of 3g 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 3g doses with 10-12 hours between the doses.

**Dental abscess:** two 3g doses with 8 hours between the doses. Gonorrhoea: single 3g 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 40mg daily, Amoxicillin 1 Gm BID, Clarithromycin 500mg BID x7 days or Omeprazole 40mg daily, Amoxicillin 750mg-1 Gm BID, Metronidazole 400mg TID x 7 days.
**Children’s dosage: (up to 10 years of age):**
Standard children’s dosage: 125mg three times daily, increasing to 250mg three times daily for more severe infections. In severe or recurrent acute otitis media, especially where compliance may be a problem, 750mg 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 scheme:

<table>
<thead>
<tr>
<th>Adults and Children over 40 kg</th>
<th>Mild impairment (creatinine clearance &gt;30 ml/min)</th>
<th>Moderate impairment (creatinine clearance 10-30 ml/min)</th>
<th>Severe impairment (creatinine clearance &lt;10 ml/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in dosage</td>
<td>500 mg b.i.d. maximum</td>
<td>500 mg/day maximum</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Children under 40 kg</th>
<th>Mild impairment (creatinine clearance &gt;30 ml/min)</th>
<th>Moderate impairment (creatinine clearance 10-30 ml/min)</th>
<th>Severe impairment (creatinine clearance &lt;10 ml/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in dosage</td>
<td>15 mg/kg b.i.d.</td>
<td>15 mg/kg o.d.</td>
<td></td>
</tr>
</tbody>
</table>

**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 (500mg for adults or 15mg/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:** 3g 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 3g Penamox orally 4 hours prior to anesthesia, followed by 3g 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 exantheticus pustulosis (AGEP) have been reported. As with other antibiotics, severe allergic reactions including angioedema, 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 and 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.

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.

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.

OVERDOSAGE

Problems of overdosage with amoxicillin are unlikely to occur. If encountered, gastrointestinal effects such as nausea, vomiting and diarrhea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria has been observed.
Amoxicillin can be removed from the circulation by hemodialysis.

**STORAGE**
Capsules and Tablets: Store in a dry place between 15-25° C.
Suspension: Keep tightly closed in a dry place below 30° C. Away from light
After reconstitution, keep in refrigerator and use within 14 days or within 7 days if stored at room temperature.

**PRESENTATIONS**

**Capsules**
PENAMOX 250 mg: Amoxicillin (trihydrate) USP 250 mg/capsule
Excipients: croscarmellose sodium, colloidal silicon dioxide, magnesium stearate.
PENAMOX 500 mg: Amoxicillin (trihydrate) USP 500 mg/capsule
Excipients: croscarmellose sodium, magnesium stearate.

**Tablets**
PENAMOX 1 g: Amoxicillin (trihydrate) USP 1 g/tablet
Excipients: povidone, croscarmellose sodium, magnesium stearate, polyethylene glycol, simethicone emulsion, mehtacrylic acid copolymer, FD&C yellow no.6 lake, hydroxypropyl methyl cellulose, purified talc, titanium dioxide.

**Suspension***
PENAMOX 125 mg/5 ml: Amoxicillin (trihydrate) USP 125 mg
Excipients: xanthan gum, methyl paraben, propyl paraben, povidone, tutti frutti powder, trisodium citrate, sodium saccharine, sucrose.
PENAMOX 250 mg/5 ml: Amoxicillin (trihydrate) USP 250 mg
Excipients: xanthan gum, methyl paraben, propyl paraben, povidone k3d, trisodium citrate, orange powder flavor, sodium saccharine, sugar.
PENAMOX 500 mg/5 ml: Amoxicillin (trihydrate) USP 500 mg
Excipients: colloidal silicon dioxide, xanthan gum, hypromellose, trisodium citrate DHD, FD&C red no.3 dye, tutti frutti powder, sucrose, sodium benzoate.
* Per 5 ml (after reconstitution)