Proposed Insert

VIAMOxx-PC3 (MY)

hovid-AMOXIGRAN GRANULES (SUGAR FREE)

DESCRIPTION
White to pale yellow grenadine flavoured granules.
White to yellowish suspension upon reconstitution.

COMPOSITION
- Amoxicillin Trihydrate equivalent to amoxicillin 125 mg/5 ml after reconstitution.
- Amoxicillin Trihydrate equivalent to amoxicillin 250 mg/5 ml after reconstitution.

PHARMACODYNAMICS
Amoxicillin is a semi synthetic penicillin which is acid resistant and bactericidal and has a similar antibacterial spectrum to ampicilin.

It has been reported that amoxicillin predominantly inhibits side-wall synthesis in susceptible bacteria while ampicilin mainly inhibits cross-wall synthesis, probably by acylation of membrane-bound transpeptidase enzymes. This prevents cross-linkage of peptidoglycan chains which is necessary for bacteria frequently occurs.

Amoxicillin has been reported to be slightly more active than ampicillin against some streptococci and salmonella spp. But less active against shigella spp. It is inactivated by penicillinase and complete cross-resistance has been reported between amoxicillin and ampicillin.

PHARMACOKINETICS
Absorption
Amoxicillin is stable to gastric acid and 50 to 90% of a dose is absorbed after oral administration; absorption is more complete than that of ampicillin and it is not greatly influenced by the presence of food.

Blood Concentration
After an oral dose of 500mg, peak serum concentrations of 3 to 20µ/ml are attained in 1 to 2 hours; detectable concentrations are present after 8 hours; peak concentrations occur earlier in children and infants by later in neonates. It is reported to produce peak plasma concentrations that are up to twice as high as those from the same dose of ampicillin.

Half-life
Serum half life, 1 hour which may be increased to 15 hours in renal failure.

Distribution
Enters most tissues and fluids but is not detectable in the cerebrospinal fluid even when the meninges are inflamed; crosses the placenta and small amounts are secreted in the milk; volume of distribution at steady-state serum concentrations, about 0.3 litres/kilogram body-weight.

It also penetrates well into purulent and mucoid sputum and low concentrations have low concentrations have been found in ocular fluid.

Protein binding
15-25% bound to plasma proteins.

Metabolic reactions
Metabolised to inactive metabolites in the liver and to 10 to 25% appears to be converted to penicilloic acid.

Excretion
About 60% of an oral dose is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion. Urinary excretion is delayed by probenecid and it also occurs more slowly in the newborn; small amounts are excreted in the bile.

INDICATIONS
For treatment of:
- Ear, nose and throat infections caused by *streptococci, pneumococci, nonpenicillinase* - producing staphylococci and *H. influenzae.*
- Genitourinary tract infections caused by *E. coli, P. mirabilis, S. faecalis.*
- Skin and soft tissues infections caused by streptococci, nonpenicillinase - producing staphylococci and *E. coli.*
- Anogenital and urethral gonorrhoea caused by *N. gonorrhoeae.*

CONTRAINDICATIONS
- Contraindicated in patients known to be sensitive to penicillin.
- Avoid in patients with infectious mononucleosis because of increased risk of skin rashes.

WARNINGS AND PRECAUTIONS
- Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, appropriate therapy should be instituted and discontinuance of amoxycillin therapy considered. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.
- Not to be used in patients with known hypersensitivity to Penicillin.

- During prolonged therapy, periodic assessment of renal, hepatic and haematopoietic function should be made as with any potent drug.
- The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Enterobacter, Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.
- Safety for use in pregnancy has not been established.

PREGNANCY AND LACTATION

Pregnancy
Limited data on the use of amoxicillin during pregnancy in humans do not indicate an increased risk of congenital malformations. Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Breast-feeding
Amoxicillin is excreted into breast milk in small quantities with the possible risk of sensitisation. Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the breast-fed infant, so the breast feeding might have to be discontinued. Amoxicillin should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

SIDE/ADVERSE EFFECTS

Hypersensitivity reactions
Rash (urticarial, erythematous, mobiliform) and less frequently, as exfoliative dermatitis or erythema multiforme.

Haemolytic effects
Haemolytic anaemia, anaemia, eosinophilia, leukopenia, neutropenia, agranulocytosis, thrombocytopenia, thrombocytopenic purpura.

G.I. effects
Diarrhoea, nausea, vomiting, black hairy tongue, glossitis, stomatitis, sore mouth or tongue.

Renal effect
Acute interstitial nephritis.

Hepatic effects
A moderate increase in serum concentration of AST (SGOT).

DRUG INTERACTIONS

- Concurrent use with allopurinol or probenecid requires careful monitoring.
- Concurrent use with chloramphenicol, erythromycins, sulphonamides and tetracycline may interfere with the bactericidal effect of amoxycillin.

OVERDOSAGE

Clinical features
Anorexia, nausea, vomiting, abdominal discomfort, diarrhoea.

Treatment for overdosage
Emesis or gastric lavage if appropriate. Symptomatic and supportive measures.

DOSAGE AND ADMINISTRATION

To reconstitute, add water to below the mark on the bottle shoulder. Invert and shake the bottle. Top up with water to the mark. Invert and shake again.

Shake well before taking each dose.

Adult:
Oral, 250 to 500 mg every eight hours; or as directed.

Children:
- Infants up to 6 kg of body weight:
  Oral, 25 - 50 mg every 8 hours.
- Infants 6 - 8 kg of body weight:
  Oral, 50 - 100 mg every 8 hours.
- Infants and children 8 - 20 kg of body weight:
  Oral, 6.7 - 13.3 mg/kg of body weight.
- Children 20 kg of body weight and over:
  See adult dose.

The information given here is limited. For further information, consult your doctor or pharmacist.

Storage:
Store below 30˚C.

After reconstitution:
Use within 10 days.
Refrigerate after reconstitution at 2˚C - 30˚C.

Presentation/Packing:
Granules 60 ml and 100 ml after reconstitution.

Product Registration Holder /
Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Malaysia.

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