

AMOXICILLIN PREMIX POWDER

500mg/g

Ingredient(s)

Each gram contains:
Amoxicillin (as Amoxicillin Trihydrate) 500mg
Sodium Benzoate (preservative) 1mg/g

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics:

Amoxicillin is an aminopenicillin. It is bactericidal against susceptible bacteria and act by inhibiting mucopeptide synthesis in the cell wall resulting in a defective barrier and an osmotically unstable spheroplast. Beta-lactam antibiotics have been shown to bind to several enzymes (carboxypeptidases, transpeptidases, endopeptidases) within the bacterial cytoplasmic membrane that are involved with cell wall synthesis. The different affinities that various beta-lactam antibiotics have for these enzymes (also known as penicillin-binding proteins; PBPs) help explain the differences in spectrums of activity the drugs have that are not explained by the influence of beta-lactamases. Like other beta-lactam antibiotics, penicillins are generally considered to be more effective against actively growing bacteria. The aminopenicillins, have increased activity against many strains of G(-) aerobes not covered by either the natural penicillins or penicillinase-resistant penicillins. Amoxicillin trihydrate is relatively stable in the presence of gastric acid. After oral administration, it is about 74~92% absorbed in humans and animals (monogastric). Food will decrease the rate, but not the extent of oral absorption. Amoxicillin serum levels will generally be 1.5~3 times greater than those of ampicillin after equivalent oral doses. After absorption the volume of distribution for amoxicillin is approximately 0.3L/kg in humans and 0.2L/kg in dogs. The drug is widely distributed to many tissues, including liver, lungs, prostate (human), muscle, bile, and ascitic, pleural and synovial fluids. Amoxicillin will cross into the CSF when meninges are inflamed in concentrations that may range from 10~60% of those found in serum. Very low levels of the drug are found in the aqueous humor, and low levels found in tears, sweat and saliva. Amoxicillin crosses the placenta, but it is thought to be relatively safe to use during pregnancy. It is approximately 17~20% bound to human plasma proteins, primarily albumin. Protein binding in dogs is approximately 13%. Milk levels of amoxicillin are considered to be low. Amoxicillin is eliminated primarily through renal mechanisms, principally by tubular secretion, but some of the drug is metabolized by hydrolysis to penicilloic acids (inactive) and then excreted in the urine. Elimination half-lives of amoxicillin have been reported as 45~90 minutes in dogs and cats, and 90 minutes in cattle. Clearance is reportedly 1.9ml/kg/min in dogs.

Indication(s):

For the control of diseases caused by *Streptococcus suis* in weaned piglets.

Target Species:

Weaned piglet

Dosage and Administration::

15mg of amoxicillin per kg of bodyweight daily for 14 consecutive days. This dose may be achieved by addition of :
1) 400 ppm in starter feed
2) 300 ppm in feed intended for piglets older than 6 weeks
Orally via mixing into feed.

Contraindication:

Penicillins are contraindicated in patients who have a history of hypersensitivity to them. Because there may be cross-reactivity, use penicillins cautiously in patients who are documented hypersensitive to other beta-lactam antibiotics (e.g., cephalosporins, cefamycins, carbapenems).

Precaution(s) / Warning(s):

Do not administer systemic antibiotics orally in patients with septicemia, shock, or other grave illnesses as absorption of the medication from GI tract may be significantly delayed or diminished.

Interaction with Other Medicaments:

- 1) In vitro studies have demonstrated that penicillins can have synergistic or additive activity against certain bacteria when used with aminoglycosides or cephalosporins.
- 2) Use of bacteriostatic antibiotics (e.g., chloramphenicol, erythromycin, tetracyclines) with penicillins is generally not recommended, particularly in acute infections where the organism is proliferating rapidly as penicillins tend to perform better on actively growing bacteria.
- 3) Probenecid competitively blocks the tubular secretion of most penicillins, thereby increasing serum levels and serum half-lives.

Pregnancy and Lactation

Penicillins have been shown to cross the placenta and safe use of them during pregnancy has not been firmly established, but neither have there been any documented teratogenic problems associated with these drugs. However, use only when the benefits outweigh the risks.

Side Effect(s) / Adverse Reaction(s):

- 1) Hypersensitivity reactions unrelated to dose can occur with these agents and can be manifested as rashes, fever, eosinophilia, neutropenia, agranulocytosis, thrombocytopenia, leukopenia, anemias, lymphadenopathy, or full blown anaphylaxis.
- 2) When given orally, penicillins may cause GI effects (anorexia, vomiting, diarrhea). Because the penicillins may also alter gut flora, antibiotic-associated diarrhea can occur, as well as selecting out resistant bacteria maintaining residence in the colon of the animal (superinfections).
- 3) High doses or very prolonged use has been associated with neurotoxicity (e.g., ataxia in dogs).
- 4) Although the penicillins are not considered to be hepatotoxic, elevated liver enzymes have been reported.
- 5) Other effects reported in dogs include tachypnea, dyspnea, edema and tachycardia.

Environmental Property

None has been mentioned in animal.

Symptoms and Treatment for Overdosage, and Antidote(s):

Acute oral penicillin overdoses are unlikely to cause significant problems other than GI distress, but other effects are possible. In humans, very high dosages of parenteral penicillins, especially in patients with renal disease, have induced CNS effects.

Shelf-Life:

4 years.

Storage Condition(s):

Store at temperature below 30°C.

Product Description and Packing(s):

A white to pale yellow color powder, and without other foreign matter
Paper bag of 10Kg

For food producing animals product:

Withdrawal Periods

Pig: 4 days

Maximum Residual Limit (MRL):

Muscle, liver, kidney, fat: 50µg/kg

To declare Y.S.P. INDUSTRIES VIETNAM CO., LTD. as Manufacturer and Y.S.P. INDUSTRIES (M) SDN. BHD. as Product Registration Holder



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