Veterinary Package Insert

Product Name:
Yen-AnMo 50% W/W Powder

Product Description:
White crystalline powder which contains 500mg of Amoxicillin Trithydrate in 1g.

Target Species:
Swine, Poultry, Others: pig, chicken broiler, duck broiler, turkey for meat production

Pharmacodynamics:
Amoxicilin is abroad spectrum betalactamic antibiotic belonging to the aminopenicillins group with bactericidal activity.
Mechanism of action
The antibacterial mechanism of action of amoxicillin consists of the inhibition of the biochemical processes of bacterial cell wall synthesis by selectively and irreversible blocking different enzymes involved in such processes, largely transpeptidase, endopeptidase and carboxypeptidase. The inadequate synthesis of the bacterial wall in susceptible species produces an osmotic imbalance which particularly affects growing bacteria (when bacterial wall synthesis processes are especially important), finally leading to lysis of the bacterial cell.
Spectrum of action
The species considered to be sensitive to amoxicillin include:
- Gram-positive bacteria:
• Streptococcus suis
- Gram-negative:
• Pasteurella spp.
• Escherichia coli
However, thebacteria which generally present resistance to amoxicillin are:
- Penicillinase-producing staphylococci.
- Some enterobacteria such as Klebsiella spp, Enterobacter spp, Proteus spp and other Gram-negative bacteria such as Pseudomonas aeruginosa.

The principal mechanism of bacterial resistance to amoxicillin is the production of β-lactamases, enzymes which inactivate the antibacterial product by hydrolysis of the β-lactam ring, thus obtaining penicillanic acid, a stable but inactive compound. Bacterial β-lactamases can be acquired via plasmids or can be constitutive (chromosomal).
These β-lactamases are exocellular in Gram-positive bacteria and found in the periplasmic space in Gram-negative bacteria.
Gram-positive bacteria are capable of producing and secreting large quantities of β-lactamases. These enzymes are encoded in plasmids which can be transferred by phages to other bacteria.
Gram-negative bacteria produce different types of β-lactamases, which remain in the periplasmic space and which are codified in the chromosome or in the plasmid.
There is complete cross-resistance between amoxicillin and other penicillins, in particular, other aminopenicillins.

Pharmacokinetics:
General:
Absorption of oral amoxicillin is independent from food intake and peak plasma concentrations are reached rapidly in most animal species, from 1 to 2 hours after the product's administration.
Amoxicillin binds sparingly to plasma proteins and rapidly spreads to the body fluids and tissues. Amoxicillin is widely distributed in the extracellular compartment. Its distribution to the tissues is facilitated by its low binding rate to plasma proteins.
The metabolism of amoxicillin is limited to hydrolysis of the β-lactam ring, leading to the release of inactive penicillanic acid (20%). Biotransformation takes place in the liver.
Most amoxicillin is eliminated through the kidneys in active form. It is also excreted in small quantities in milk and bile.
Chicken Broiler:
Oral bioavailability is about 67%. Maximum plasma concentration is reached in around one hour. It is well and quickly distributed in the organism, with low binding to plasma proteins (17-20%).
Pigs:
After the administration of the product at the recommended dose in drinking water, plasma concentrations ranged from 0.53 µg/ml (Cmax) to 0.27 µg/ml (Cmin). Steady state was reached 10 hours after the first administration."

Indications:
Chicken broiler, duck broiler and turkey for meat production: Treatment of pasteurellosis and colibacillosis caused by strains of Pasteurella spp. and Escherichia coli sensitive to amoxicillin
Pig: Treatment of infections caused by strains of Streptococcus suissensitive to amoxicillin.

Recommended Dosage:
In drinking water use.
Dosage and treatment regimen
-Pig: 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 4 days.
-Chicken broilers: 15 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 30 mg product/kg bodyweight/day) for 5 days.
-Duck broilers: 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 3 days.
-Turkeys for meat production: 15 to 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 30-40 mg product/kg bodyweight/day) for 5 days.
The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of amoxicillin has to be adjusted taking into account the daily waterconsumption.
Based on the dose to be used, and the number and weight of the animals to be treated, the exact daily amount of product can be calculated using the following formula:

$$\text{g of product/ litre of drinking water/day} = \frac{\text{Mean bodyweight (kg) of animals x dose (mg amoxicilin trihydrate/kg bw/day)}}{\text{Mean daily water consumption (litres) x 500}}$$

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
No other source of drinking water should be available during the medication period. Medicated drinking water should be refreshed every 24 hours.
After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance,
The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment.

Mode of Administration:
Oral

Contraindications:
Do not use in rabbits, hamsters, gerbils and guinea pigs.
Do not use in ruminants and horses.
Do not use in known cases of hypersensitivity to penicillins or to other β-lactam antibiotics.
Do not treat infections caused by bacteria producing the enzyme beta lactamase.

Warning and Precautions:
Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the bacteria isolated from the animals. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for crossresistance.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
Take the necessary action to prevent the powder from spreading while the product is being added to drinking water.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.
Avoid contact with the skin and eyes. Wear gloves, overalls and goggles during preparation and administration of medicated water or liquid feed. In case of contact, rinse with plenty of clean water.
Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.
Do not smoke, eat or drink while handling the product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Interactions with Other Medicaments
Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines, macrolides and sulphonamides) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

Pregnancy and Lactation:
Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Adverse Effects:
In very rare cases the following adverse reactions may appear:
-Hypersensitivity reactions may occur, the severity varying from skin rash to
anaphylactic shock.
-Gastrointestinal symptoms(vomiting, diarrhoea).

Symptoms and Treatment of Overdose:
No side effects were observed after administration at 5 times the recommended dosage. Treatment should be symptomatic and no specific antidote is available.

Withdrawal Period:
Meat and offal:
Pig: 6 days
Chicken broilers: 1 day
Duck broilers: 9 days
Turkeys for meat production: 5 days
Eggs: Not authorised for use in birds producing eggs for human consumption.Do not use within 4 weeks before the onset of the laying period.

Packaging:
Packed in 100gm aluminium foil, 1kg aluminium foil or 25kg HDPE plastic bag

Storage Condition:
Store below 30°C in dry place, protected from light.

Shelf Life
Two years from date of manufacturing
To be used within 24 hours after first opening of container.
To be used within 24 hours after dilution.

Product Registration Holder
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