Veterinary Package Insert

OXYTETRAVET 50% W/W PREMIX POWDER

PRODUCT DESCRIPTION

Pale yellow to pale brown colour powder, which contains 54% of oxytetracycline dihydrate (equivalent to 50% of oxytetracycline), i.e. 540mg of oxytetracycline dihydrate (equivalent to 500mg of oxytetracycline) in 1g.

PHARMACODYNAMICS & PHARMACOKINETICS

Oxytetracycline binds reversibly to receptors of the 30S ribosomal fraction. This leads to a blocking of the binding of aminoacyl-tRNA to the corresponding site of the ribosome complex messenger-RNA. This results in inhibition of protein synthesis and therefore a growth arrest of the bacterial culture. Oxytetracycline is primarily bacteriostatic. The bacteriostatic activity of oxytetracycline involves penetration of the substance into the bacterial cell. The penetration of oxytetracycline is exercised by both passive and active dissemination. The main possible resistance mode is related to the presence of an R factor which is responsible for a decrease in active transportation oxytetracycline. Oxytetracycline is a broad spectrum antibiotic. It is primarily active against microorganisms Gram positive and negative, aerobic and anaerobic, and against mycoplasma, Chlamydia and Rickettsiae. The acquired resistance to oxytetracycline has been reported. Such resistance is usually of plasmid origin. Cross resistance to other tetracyclines is possible. Continuous treatment with low doses of oxytetracycline may also result in increased resistance to other antibiotics.

For the majority of species, oxytetracycline is quickly (2-4 hours) absorbed after oral administration in animals fasted and its bioavailability is between 60% and 80%. The bioavailability may decrease in the presence of food in the stomach because oxytetracycline forms insoluble chelates with divalent or trivalent cations (Mg, Fe, Al, Ca). In pigs, the influence of food is negligible as the bioavailability of oxytetracycline is less than 5%. Oxytetracycline binds to plasma proteins variably depending on the species (20-40%). Its distribution is wide. Oxytetracycline diffuses throughout the body where higher concentrations are found in the kidneys, liver, spleen and lungs. Oxytetracycline crosses the placenta. Oxytetracycline is excreted unchanged mainly via urine. It is also excreted in the bile, but a large percentage of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

INDICATION

In pigs:

Treatment and Prevention infected areas of respiratory infections and digestive infections caused by susceptible germs to oxytetracycline.

RECOMMENDED DOSAGE AND ADMINISTRATION

In pigs:

Infected prevention in: 25 mg oxytetracycline (0.05g of product) per kg body weight per day, orally, for 10 days.

Treatment: 50 mg oxytetracycline (0.1g of product) per kg body weight per day, orally, for 10 days.

Incorporation rate the amount of medicated feed consumed by the animals depends on their physiological state (age ...) and clinical. To meet the recommended doses oxytetracycline and consider the food ingested workforce, the incorporation rate can be increased or possibly reduced to the minimum incorporation limit of 1kg/tonne. This can lead to different ppm oxytetracycline levels in medicated feed those mentioned below indication.

For daily feed intake of 50 g of food per kg bodyweight, this dosage corresponds, prevention, 500 ppm of oxytetracycline in the feed, is an incorporation rate of 1 kg of medicated premix per tonne of feed and treatment at 1000 ppm, an incorporation rate of 2 kg of medicated premix per tonne of feed.

CONTRAINDICATIONS

Do not use in cases of known allergy to oxytetracycline or other substance tetracycline.

Do not use in case of known resistance to tetracyclines.

WARNINGS & PRECAUTIONS.

Special precautions for use in animals:

The premix is intended to be used for medicated feed and it cannot be used other than intended. The incorporation rate of the premix to the feed can be less than 1kg/tonne.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not handle this product in case of known allergy to tetracyclines.

If there is reaction after exposure to the product (eg. rash), consult a doctor.

INTERACTIONS WITH OTHER MEDICATIONS

Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines. The tetracyclines should not be administered with antacids, gels based on aluminum, preparations based mineral as insoluble complexes are formed, which reduce the absorption of the antibiotic.

PREGNANCY AND LACTATION

The oxytetracycline showed no sign of embryotoxicity or teratogenicity in laboratory animals. In mammals, oxytetracycline through the placenta, causing tooth staining and slower fetal growth. The tetracyclines are found in breast milk. The safety of the product has not been evaluated in pregnant and lactating animals. The use of the product in pregnant and lactating animals should be evaluated the by the veterinarian over the benefit and risk.

ADVERSE EFFECTS

As for all tetracyclines, adverse effects were noted including gastrointestinal disturbances and less frequently allergic reactions and photosensitivity.

OVERDOSE & TREATMENT

No specific antidote is available.

WITHDRAWAL PERIOD

Meat and offal: 14 days.

MAXIMUM RESIDUAL LIMIT (MRL)

Substance	Target Tissues (all food producing species)	Maximum Residue Limits (MRLs) in µg/kg
Chlortetraycline	Fat	10
	Muscle	100
	Liver	300
	Kidney	600

STORAGE CONDITION

Store below 30°C. Protect from direct sunlight.

SHELF LIFE

2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

PACKING

100gm
1000gm
25kg

LIM SENG PHARMACHEM SDN. BHD.
(product registration holder)
2692, Tingkat Perusahaan Enam,
Prai Industrial Estate MK1,
13600 Prai,
Pulau Pinang.

THYE PHARMA SDN. BHD.
(manufacturer)
No.2 Lorong Industri Ringan Permatang Tinggi 8,
Kawasan Industri Ringan Permatang Tinggi,
14000 Bukit Mertajam,
Pulau Pinang.

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