Veterinary Package Insert

OXYTETRAVET HCL 50% W/W WATER SOLUBLE POWDER (50% Oxytetracycline Hydrochloride)

PRODUCT DESCRIPTION

Yellow colour powder, which contains 50% of Oxtetracycline Hydrochloride (equivalent to 46.3% of Oxytetracycline), i.e. 500mg of Oxytetracycline Hydrochloride (equivalent to 463mg of Oxytetracycline) in 1 gm.

PHARMACODYNAMICS & PHARMACOKINETICS

The oxytetracycline links reversibly to the ribosomal subunit 30S receptors, this leading to a blockage of the union between aminoacyl-tRNA to the site corresponding to the mRNA-ribosome complex messenger. It results in an inhibition of the protein synthesis and inhibits bacterial growth. The mainly bacteriostatic activity of oxytetracycline involves uptake of the substance into the bacterial cell which occurs by both passive and active diffusions. The main mechanism of resistance is due to the possible presence of a R factor responsible for a decrease in the active transport of oxytetracycline.

Oxytetracycline is a broad-spectrum antibiotic. It is mainly active against Gram-positive and Gram negative bacteria, aerobic and anaerobic, as well as against mycoplasma, the Chlamydia and Rickettsiae.

The oral absorption of oxytetracycline is low. The mean values of oral absorption of oxytetraycline are 3-5% in pigs and 48% in turkeys.

This bioavailability can be reduced in the presence of food in the stomach as oxytetracycline leads to the formation of insoluble chelates with divalent or trivalent cations (Mg, Fe, Al, Ca).

In pigs, the influence of food is negligible on the bioavailability of oxytetracycline which is less than 5%.

The oxytetracycline binds variably to plasma proteins according to the species (75%) (Its distribution is large. The oxytetracycline diffuses throughout the body, the highest concentrations have been found in the kidneys, liver, spleen and lungs. The oxytetracycline crosses the placental barrier.

Oxytetracycline is excreted unchanged mainly via urine. It is also excreted via bile but a high proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

INDICATION

In chickens (broilers, breeding hens) and pigs

Treatment and prevention at the group level of septicaemia, respiratory and gastrointestinal infections caused by bacteria sensitive to oxytetracycline, where the presence of disease in the group has been confirmed.

RECOMMENDED DOSAGE AND ADMINISTRATION

The product is recommended for oral administration in drinking water.

The duration of treatment is 3 to 5 days, for both chickens and pigs.
Dosing is presented in the following table:

Species	mg of oxytetracycline / kg of bodyweight / day	mg of product / 10 kg of bodyweight / day	Estimated water consumption (L / kg of bodyweight)	mg of product / L of drinking water
Pigs	20 mg	432 mg	1 L / 10 kg	432 mg
Chickens	20 mg	432 mg	1 L / 5	216 mg

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of oxytetracycline should be calculated according to the following formula:

$$\frac{\text{mg oxytetracycline / kg body weight / day} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (L) per animal}} = \text{mg oxytetracycline per litre drinking water}$$

CONTRAINDICATIONS

Do not use in case of hypersensitivity to oxytetracycline or any other substance from tetracyclines group.

Do not use in cases of known oxytetracycline resistance

WARNINGS & PRECAUTIONS.

Special precautions for use in animals:
This powder should be dissolved in water, before use.

Use of the product should be based on susceptibility testing of bacteria isolate from the animal. If 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 the oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.

Prolonged or repeated use should be avoided as these practises can enforce development and spread of the bacterial resistance. This is particularly likely in enterobacteria and Salmonella spp., many of which are already resistant.

As eradication of the target pathogens may not be achieved, medication should be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Extensive resistance to oxytetracycline has been recognised in porcine and poultry isolates of strains form E. Coli, Salmonella spp., Campylobacter spp., and Enterococcus spp. The product should only be used where culture and sensivity testing have demonstrated that it is likely to be effective.

Sick animals may have a reduced appetite and an altered drinking pattern and should, if necessary, be medicated parenterally.

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

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Avoid inhaling dust when handling the product until complete solubilisation in water. Use in a well-ventilated area away from draughts.

Avoid contact with skin and eyes.

Personal protective equipment consisting of latex and nitrile gloves, eye protection dust mask (either a disposal half-mask respirator or a non-disposable respirator) and suitable protective clothing should be worn when handling the veterinary medicinal product. In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water. If irritation occurs, seek medical advice immediately and show the label to the physician.

Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands and contaminated skin immediately after handling the product.

Do not smoke, eat or drink while handling the product.

INTERACTIONS WITH OTHER MEDICATIONS

Divalent or trivalent cations (Mg, Fe, Al, Ca) may chelate with tetracyclines. The tetracylines should not be administered with antacids, gels containing aluminium, preparations containing vitamins or minerals as insoluble complexes will be formed, which decreases the absorption of the antibiotic.

PREGNANCY AND LACTATION

Laboratory studies in animals have not produced any evidence of embryotoxicity or teratogenic effects.

In mammals, oxytetracycline pass the placental barrier, resulting in staining of teeth and slow foetal growth.

Tetracyclines are found in breast milk.

Use only according to the benefit/risk assessment by the responsible veterinarian.

ADVERSE EFFECTS

As for all other tetracyclines, side effects have been observed such as gastro-intestinal disorder and less frequently, allergic and photosensitivity reactions.

OVERDOSE & TREATMENT

None known.

WITHDRAWAL PERIOD

Meat and offal: 7 days.

Eggs: do not use in laying birds producing eggs intended for human consumption.

MAXIMUM RESIDUAL LIMIT (MRL)

Substance	Food	Maximum Residue Limits (MRLs) in µg/kg
Oxyrtetraycline	Fat (chicken, pig)	10
	Muscle (chicken, pig)	100
	Egg (chicken)	200
	Liver (chicken, pig)	300

	Kidney (chicken, pig)	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

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