

NEO-Oxytet 10% w/w Water Soluble Powder

FOR ANIMAL USE ONLY

Brand or Product Name :

NEO-Oxytet 10% w/w Water Soluble Powder

Name and Strength of Active Substance(s)

Each kg contains : 50 g of oxytetracycline hydrochloride and 50 g neomycin sulphate.

Product Description

NEO-Oxytet 10% w/w Water Soluble Powder is a light creamy yellow powder.

Pharmacodynamics Properties

Oxytetracycline is a tetracycline derivative obtained from *Streptomyces rimosus*. Oxytetracycline generally acts as bacteriostatic antibiotic and inhibit protein synthesis by reversibly binding to 30S ribosomal subunits of susceptible organisms. This binding effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting bacterial protein synthesis. Oxytetracycline also is believed to reversibly bind to 50S ribosomes and additionally alter cytoplasmic membrane permeability in susceptible organisms. Oxytetracycline is a broad-spectrum antibiotics. It has activity against Gram-positive and gram-negative aerobic and anaerobic bacteria, including *Brucella*, *Coxiella*, *Ehrlichia*, some *Mycobacterium*, *Mycoplasmas*, *Chlamydiae*, *Rickettsias*, and protozoa. Neomycin is an aminoglycoside antibiotic. It acts on susceptible bacteria by irreversibly binding to the 30S ribosomal subunit thereby inhibiting protein synthesis. It is considered to be a bactericidal antibiotic. Neomycin's spectrum of activity include coverage against many aerobic Gram-negative bacteria, including most species of *E.coli*, *Klebsiella*, *Proteus*, *Salmonella* and *Enterobacter*.

Pharmacokinetics Properties

Oxytetracycline is readily absorbed after oral administration to fasting animals. Bioavailability are approximately 60 – 80 %. The presence of food or dairy products can reduce the amount of oxytetracycline absorbed. Oxytetracycline is widely distributed in the body, including to the heart, kidney, lungs, muscle, pleural fluid, bronchial secretions, sputum, bile, saliva, urine, synovial fluid, ascetic fluid, and aqueous and vitreous humor. Only small quantities of oxytetracycline is distributed to the CSF. Oxytetracycline crosses the placenta, enter fetal circulation and are distributed into milk. The volume of distribution of oxytetracycline is approximately 2.1 L/kg in small animals, 0.8 L/kg in cattle. The amount of plasma protein binding of oxytetracycline is about 10 – 40%. Oxytetracycline is eliminated unchanged primarily via glomerular filtration. The drug is not metabolized, but is excreted into GI tract via biliary and nonbiliary routes and may become inactive after chelation with fecal materials. Neomycin is not appreciably absorbed (only about 3%) after oral administration. Patients receiving oral neomycin with hemorrhagic or necrotic enteritis (bowel wall is damaged) may absorb appreciable quantities of the drug. Orally administered neomycin is nearly all excreted unchanged in the feces.

Indication

Swine: Bacterial enteritis (scours), swine dysentery and salmonellosis, Bacterial Respiratory Infections (pneumonia, pasteurellosis)

Calves : Scours (bacterial enteritis, calf scours), Bacterial Respiratory Infections (pneumonia, pasteurellosis)

Chickens and Turkeys : Chronic Respiratory Diseases, Bluecomb* and bacterial enteritis and Stress conditions.

* Turkey only

Recommended Dosage

	Species / Indication	Dose
1	Swine	
	Bacterial enteritis (scours), swine dysentery and salmonellosis	Treatment : Mix 2g /L of drinking water for 4 – 5 days. Prevention : Mix 1g /L of drinking water for 4 – 5 days.
	Bacterial Respiratory Infections (pneumonia, pasteurellosis)	Treatment : Mix 4g /L of drinking water for 4 – 5 days.
2	Calves	
	Scours (bacterial enteritis, calf scours)	Treatment : mix 2g/L of drinking water for 4 – 5 days. Prevention : mix 1g /L of drinking water for 4 – 5 days.
	Bacterial Respiratory Infections (pneumonia, pasteurellosis)	Treatment : mix 4g /L of drinking water for 4 – 5 days.
3	Chickens and Turkeys	
	Chronic Respiratory Diseases	Treatment : mix 2g in 1 - 2L of drinking water for 3 – 5 days. Prevention : mix 2g in 1 - 2L drinking water for the first 3 days, and for 1 day at each feed change (starter to grower).
	Bluecomb* and bacterial enteritis (* Turkey only)	Treatment : mix 2g in 1 - 2L of drinking water for 3 days. Stop for 2 days, then treat for 2 more days if improvement is not noted. Prevention : mix 1g /L of drinking water for 3 – 5 days.
	Stress conditions	Treatment : mix 2g in 1 - 2L of drinking water for 3 – 5 days.

Direction of Use

Powder is to be dissolved in animal drinking water and administered orally. Mixing Directions : To assure thorough dissolution, place the **NEO-Oxytet 10%w/w Water Soluble Powder** in a small mixing container and add 25 Litres of water . Stir until all the powder completely dissolved. Mix this concentrated stock solution with water to make the final volume of medicated drinking water. Prepare fresh medicated solution daily.

Contraindications

Hypersensitivity to any tetracycline and aminoglycosides. Contraindicated in the presence of intestinal obstruction, Contraindicated in rabbits and hares. Do not use in calves to be process to veal. Do not use in laying birds.

Precautions

Special precautions for person administering the products : Care should be taken to avoid accidental ingestion. In case of accidental ingestion, wash out mouth immediately with water and seek medical advice. May cause irritation or sensitisation by skin contact. Avoid contact with skin and eyes. In case of accidental spillage onto the skin or eyes, rinse the affected area with clean running water. Seek medical advice if irritation persists. People with a known sensitivity to the ingredients in this product should avoid using the product. Wear overalls and impervious gloves when mixing and handling the product. Wash hands and exposed skin after handling the product. Do not eat, drink or smoke when handling this product.

Interactions with Other Medicaments

When orally administered, tetracyclines can chelate divalent or trivalent cations which can decrease the absorption of the tetracyclines or the other drug if it contains these cations. It is recommended that all oral tetracyclines be given at least 1 -2 hours before or after the cation-containing product. Use with cautions with other nephrotoxic, ototoxic and neurotoxic drugs. These include amphotericin B, other aminoglycosides, acyclovir, bacitracin (parenteral use), cisplatin, methoxyflurane, polymyxin B or vancomycin. Concurrent use with loop (furosemide, ethacrynic acid) or osmotic diuretics (mannitol, urea) may increase the nephrotoxic or ototoxic potential of neomycin. Concomitant use with general anesthetics or neuromuscular blocking agents could potentiate neuromuscular blockade.

Statement on usage during pregnancy and lactation

No adverse effect

Adverse Effects / Undesirable Effects

The most common adverse reactions include gastrointestinal upset : nausea, vomiting, diarrhea and anorexia. Use of tetracycline during the tooth development, even during late pregnancy leads to tooth discolouration.

Overdose and Treatment

Tetracyclines are generally well tolerated after acute overdoses. Manifestations of an acute overdosage would most likely be associated with GI distress (nausea, anorexia, vomiting, diarrhea). Should the animal develop severe emesis or diarrhea, fluid and electrolytes should be monitored and replaced if necessary.

Rarely, oral neomycin will cause ototoxicity, nephrotoxicity, severe diarrhoea, and intestinal malabsorption.

Withdrawal Period(s)

Chickens : 7 days ; Turkeys and swine : 14 days ; Calves : 30 days.

Shelf-life

3 years in the original packing. Any opened sachet and unused medicated water to be discarded after 24 hours.

Allowable Maximum Residual Limit (MRL)

Neomycin : Muscle, liver, fat (chicken, turkey, duck, cattle, goat, sheep and pig), egg (chicken), milk (cattle) = 500µg/kg, Kidney (chicken, turkey, duck, cattle, goat, sheep and pig) = 1000 µg/kg.

Oxytetracycline : Fat (cattle, sheep, pigs, chicken and turkey) = 10 µg/kg, egg (chicken) = 200 µg/kg , Milk (cattle), muscle (cattle, sheep, pigs, chicken and turkey) = 100 µg/kg, Liver (cattle, sheep, pigs, chicken and turkey) = 300 µg/kg, Kidney (cattle, sheep, pigs, chicken and turkey) = 600 µg/kg [Ref. REGOV, Version 2, dated Dec 2009]

Storage Conditions

Store in a dry place below 25°C. Keep out of reach of children. Jauhi ubat dari kanak-kanak. Any opened sachet or unused medicated water to be discarded after 24 hours.

Disposal of Containers

Traces of medicated powder left in an opened aluminum sachet can be rinsed out with clean animal drinking water and use in animal treatment. Cleaned aluminum sachet can be safely disposed in trash according to local government regulations.

Dosage Forms and packaging available

Available in 200g, 500 g and 1 kg aluminum sachet.

Name and Address of manufacturer

Life Biopharma Sdn. Bhd. (company no. 546163-D)

No. 250-251, Jalan Industri Galla 13, Kawasan Perindustrian Galla, 70200 Seremban, Negeri Sembilan, Malaysia.

Date of Revision of Package Insert

2014-01-09