T-LOX 1000 MG/G GRANULES

T-LOX 1000 mg/g Granules appears to be a light yellow color granules.

Composition
Each 1.1 g of granules contains
Tylosin (as Tylosin tartrate)……1000gm

Pharmacodynamics
Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible microorganisms.
The tylosin spectrum of activity includes amongst others Gram-positive bacteria, some Gram – negative strains such as *Pasteurella*, and *Mycoplasma* spp.

Pharmacokinetics
In most species peak plasma concentrations have been attained 1 to 2 hours after administration of tylosin. Compared to plasma levels clearly higher tissue concentrations have been observed. Tylosin was extensively metabolised.

Indications
Calves: Treatment and metaphylaxis of pneumonia caused by *Mycoplasma* spp when the disease has been established in the herd.
Pigs: Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis* when the disease has been established in the herd.
Treatment and metaphylaxis of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis* when the disease has been established in the herd.
Chickens: Treatment and metaphylaxis of chronic respiratory diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been established in the flock.
Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* when the disease has been established in the flock.
Turkeys: Treatment and metaphylaxis of infectious sinusitis caused by *Mycoplasma gallisepticum*. when the disease has been established in the flock.

Dosage
Oral administration through the drinking water
In calves the product can also be administered through milk or milk replacer. 1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:
Calves:
10 – 20 mg tylosin (corresponding to 11 – 22 mg of product) per kg BW, twice daily (corresponding to a daily dose of 20 – 40 mg tylosin per kg BW), for 7 - 14 days.
Turkeys:
75 – 100 mg tylosin (corresponding to 82.5 – 110 mg of product) per kg BW per day for 3 – 5 days.
Chickens:
For the treatment of chronic respiratory disease:
75 – 100 mg tylosin (corresponding to 82.5 – 110 mg of product) per kg BW per day for 3 – 5 days.
For the treatment of necrotic enteritis:
20 mg tylosin (corresponding to 22 mg of product) per kg BW per day for 3 days.
Pigs:
For the treatment of enzootic pneumonia:
20 mg tylosin (corresponding to 22 mg of product) per kg BW per day for 10 days.
For the treatment of ileitis or PIA:
5 – 10 mg tylosin (corresponding to 5.5 - 11 mg of product) per kg BW per day for 7 days.

For the preparation of the medicated water/milk/milk-replacer the body weight of the animals to be treated and their actual daily water/milk/milk-replacer consumption should be taken into due account. Consumption may vary depending on factors like age, state of health, breed, husbandry system. To provide the required amount of active substance in mg per litre drinking water/milk/milk-replacer the following calculation should be made:

$$\frac{\text{… mg tylosin per kg bodyweight per day} \times \text{Average bodyweight (kg) of the animals to be treated}}{\text{Average amount of drinking water or milk / animal (L)}} = \text{…mg tylosin / L of drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.
Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. 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 which might support development of resistance.
Medicated water, milk or milk replacer should be replaced every 24 hours. If individual animals show signs of a serious infection such as a reduced water or feed intake, then they should be treated individually, such as by injection.

Contraindications
Do not use in animals with known hypersensitivity to tylosin or other macrolides.

Do not use in cases of known resistance to tylosin or cross-resistance to other macrolides (MLS-resistance).
Do not use in animals vaccinated with tylosin-sensitive vaccines either at the same time or within 1 week previously.
Do not use in animals with hepatic disorders.
Do not use in horses because of danger for inflammation of the caecum.

Special warnings for each target species
Due to likely variability (time, geographical) in susceptibility of bacteria to tylosin, bacteriological sampling and susceptibility testing are recommended.
Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

Special precautions for use
Special precautions for safe use in animals
Animals with acute infections may have a reduced water and feed consumption and should be treated with a suitable injectable veterinary medicinal product first. Do not leave or dispose of water containing tylosin tartrate where it may be accessible to either animals not under treatment or wildlife.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided. To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator. Wash hands after use.
In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water. Do not handle the product if you are allergic to ingredients in the product. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Interactions with Other Medicaments
Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

Pregnancy and Lactation
Laboratory studies in mice and rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. No studies have been conducted in the target species. Use only according to the benefit/risk assessment by the responsible veterinarian.

Side Effects
Pigs:

Undetermined frequency (cannot be estimated from the available data)	Diarrhoea*,pruritus*, reddening of the skin*, swollen vulva*, rectal oedema* and rectal prolapse*

* all transient and appear 48-72 hours after start of the treatment
Reporting adverse events is important. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority.

Overdose and Treatment
There is no evidence of tylosin toxicity in rats, at dose rates of up to 1000 mg/kg by the oral route. There is no evidence of tylosin toxicity in chickens, turkeys, pigs or calves when administered orally at up to three times the recommended dose.

Withdrawal Period(s)
Calves (meat and offal): 12 days.
Pigs (meat and offal): 1 day.
Turkeys (meat and offal): 2 days.
Turkey (eggs): Zero days.
Chickens (meat and offal): 1 day.
Chicken (eggs): Zero days.

Storage Conditions
Store below 30°C. Protect from heat and sunlight exposure.
Keep out of reach of children/ Jauhkan daripada kanak-kanak.
Any unused product or packaging should be disposed of in accordance with local legislation.
Shelf Life after first opening: 7 days.
Shelf life after dilution: 24 hours.

Packaging Available
110g, 220g, 550g, 1.1kg

Product holder and Manufacturer
Nam Pharma Sdn. Bhd.
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Taman Perindustrian Antarabangsa IGB,
31200 Chemor, Perak, Malaysia.

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