



TYLO PLUS 1000mg/g Granules

MAL no.:

Active Ingredient:

Each 1.1 gram contains
Tylosin (as tartrate) ----- 1000.0mg

Product Description:

Almost white to slightly yellow granules which can be dissolved in animal drinking water.

Dosage form:

Water soluble granules

Pharmacodynamics:

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms. 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.

Environmental properties

Most of the residues are excreted in faeces predominantly consisting of tylosin (factor A), relomycin (factor D) and dihydrodesmycosin.

Indication:

Cattle (Calves): Treatment and prevention of pneumonia caused by *Mycoplasma spp* when the disease has been established in the herd.

Pigs: Treatment and prevention of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis* when the disease has been established in the herd.

Treatment and prevention of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis* when the disease has been established in the herd.

Chickens: Treatment and prevention of chronic respiratory diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been established in the flock.

Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens* when the disease has been established in the flock

Turkeys: Treatment and prevention of infectious sinusitis caused by *Mycoplasma gallisepticum* when the disease has been established in the flock.

Mode of Administration:

Oral administration via drinking water.

Recommended Dosage:

Oral administration through the drinking water. In cattle (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:

Cattle (Calves):

10-20 mg tylosin per kg BW (corresponding to 11-22 mg of the veterinary medicinal 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 per kg BW per day (corresponding to 82.5-110mg of the veterinary medicinal product per kg BW) for 3-5 days.

Chickens:

For the treatment of chronic respiratory disease: 75-100 mg tylosin per kg BW per day (corresponding to 82.5-110 mg of the veterinary medicinal product per kg BW) for 3-5 days.

For the treatment of necrotic enteritis:

20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product) for 3 days.

Pigs:

For the treatment of enzootic pneumonia:

20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product per kg BW) for 10 days.

For the treatment of ileitis or PIA:

5-10 mg tylosin per kg BW per day (corresponding to 5.5-11 mg of the veterinary medicinal product per kg BW) for 7 days.

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water/ milk/ milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of tylosin may need to be adjusted accordingly. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$x \text{ mg product per kg bodyweight per day} \times \text{Average bodyweight (kg) of animal to be treated} = \text{Average amount of drinking water or milk per animal (l) per litre of drinking water}$$

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 cases of hypersensitivity to the active substance or to 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:

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 Safe Use in the Target Species:

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 a mask. 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.

Usage during 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.

Adverse Effects:

Pigs

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| Undetermined frequency (cannot be estimated from the available data) | Diarrhoea*, pruritus*, reddening of the skin*, swollen vulva*, rectal oedema* and rectal prolapse* |
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* All transient and appear 48-72 hours after start of the treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

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 Periods:

Cattle (Calves) (Meat and Offal) - 12 days

Pigs (Meat and Offal)- 1 day

Turkeys (Meat and Offal)- 2 days; Turkey (eggs) - 0 days

Chickens (Meat and Offal)- 1 day; Chickens (eggs) - 0 days

Storage Condition:

Store in a cool and dry place (< 30°C). Protect from light.

Shelf Life:

36 months

Shelf Life after Opening:

Discard any unused product immediately after opening

Shelf Life after Dilution/Reconstitution:

24 hours

Packaging Available:

110g/packet, 100packets/carton, 11kg/carton;

550g/packet, 30packets/carton, 16.5kg/carton;

1.1kg/ packet, 20packets/carton, 22kg/carton;

Manufacturer:

N.S. Laboratory Sdn. Bhd.

54, Jalan S2C2, Green Technology Park, Seremban 2, 70300 Seremban, Negeri Sembilan, Malaysia.

Registration Holder:

GNC Agritech Sdn. Bhd.

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Revised Date:

26/11/2025