

PRODUCT INFORMATION LEAFLETS (PIL)

Prima Tylo 50 Powder

Composition:

Each Kg contains: 500g Tylosin Phosphate (equivalent to 452g Tylosin)

Description: light yellow color powder

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

Indication:

Swine

For treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

Broiler and Replacement Chickens

To aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum*.

Recommended Dose:

Swine

Amount: Tylosin, 40-100 grams per ton of feed.

Indications: For treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*.

Limitations: As tylosin phosphate. Administer in feed as tylosin phosphate after treatment with tylosin tartrate in drinking water; 250 milligrams per gallon in drinking water for 3-10 days, 40-100 grams (corresponding to 88g – 221g Prima Tylo 50) per ton in feed for 2-6 weeks. Feed continuously as the sole ration when feeding Prima Tylo 50.

Broiler and Replacement Chickens:

Amount: Tylosin, 800 - 1000 grams (corresponding to 1770g – 2212g Prima Tylo 50) per ton of feed for broiler chickens; 1000 grams (corresponding to 2212g Prima Tylo 50) per ton of feed for replacement chickens.

Indications: To aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum*.

Limitations: As tylosin phosphate. Administer in the feed to chickens 9 to 5 days of age follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age. Feed continuously as the sole ration.

Mode of administration:

Oral

Contraindication:

- Do not use in animals with known sensitivity to the active substance and/or to any of the excipients of the veterinary medicinal product,
- Do not use in animals with known hyper sensitivity to tylosin and other macrolides,
- Do not use where cross-resistance to other macrolides (MLS-resistance) is suspected
- 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. Danger of inflammation of the cecum.

Warning and Precaution:

Special warnings (for each target species)

None.

Special precautions for use

Special precautions for use in animal

i. Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable product first.

'Due to likely variability (time, geographical) in susceptibility of bacteria for tylosin, bacteriological sampling and susceptibility testing are recommended.'

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to Tylosin and other macrolides

In farms which have recurring problems with swine dysentery, farm management, livestock husbandry and hygiene should be examined to avoid repeated administration of antimicrobial substances. An eradication procedure should be taken into account.

ii. Special precautions for 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 feed, wear overalls, safety glasses, impervious gloves, and wear either a disposable half mask respirator or a non-disposable respirator with a filter. 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.

Interaction with other medicaments:

Lincosamides and aminoglycoside antibiotics antagonize 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 population. Use only according to the benefit/risk assessment by the responsible veterinarian.

Side Effects:

In pigs, adverse reactions have been observed, including diarrhoea, pruritus, erythema, rectal oedema and prolapse.

Symptoms and Treatment of Overdose:

Tylosin has been shown to produce no adverse effects when fed to pigs at 600 ppm in the feed (three to six times the recommended dose level) for 28 days. At high levels diarrhoea, apathy, convulsions may occur. The therapy is symptomatic.

Withdrawal Period:

Withdraw 5 days before slaughter when fed to chickens at 800 to 1000g (corresponding to 1770g – 2212g Prima Tylo 50) per ton.

Storage Condition:

Stored in the original packing @ 25°C±2, in dry and well-ventilated facilities, protected from direct sunlight.

Dosage form & packaging: powder, 10kg plastic drum

Manufacturer name & address:

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Marketed by:

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