TYLONE-P 668MG PREMIX

FOR ANIMAL USE ONLY

Brand or Product Name :

TYLONE-P 668MG PREMIX

Name and Strength of Active Substance(s)

Each gram contains 668 mg Tylosin Phosphate which is equivalent to 603 mg Tylosin base.

Product Description

An off-white to light yellowish powder for medicated feeding stuff.

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. at concentrations of 16µg/ml or less.

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

Pigs: Treatment and prevention of Porcine Intestinal Adenomatosis (PIA) associated with Lawsonia intracellularis when the disease has been diagnosed at the group or herd level, Broilers and pullets: Treatment and prevention of respiratory infections caused by Mycoplasma gallisepticum and Mycoplasma synoviae, when the disease has been diagnosed in the flock. Treatment and prevention of necrotic enteritis caused by Clostridium perfringens, when the disease has been diagnosed in the flock.

Recommended Dosage

To be mixed thoroughly with feed.

Pigs :

For the treatment and prevention of porcine intestinal adenomatosis (PIA):

7 – 8 mg TYLONE-P 668MG PREMIX per kg bodyweight for 3 weeks.

Broilers and pullets:

For the treatment and prevention of respiratory infections:

214 mg TYLONE-P 668MG PREMIX per kg bodyweight for the first 5 days of life. It is strongly recommended to repeat the treatment of the birds at the age of 3-4 weeks.

For the treatment and prevention of necrotic enteritis:

17 – 34 mg TYLONE-P 668MG PREMIX per kg bodyweight for 7 days.

Direction of Use: For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily feed consumption should be taken into due account. Consumption may vary depending on factors like age, breed, husbandry system. To provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:

$$\frac{\text{mg product /kg bodyweight/day}}{\text{Average daily amount of mixed feed intake /kg per animal}} \times \text{average bodyweight (kg) of the animals to be treated} = \text{mg product/kg mixed feed}$$

The mixing should be performed by an (authorised) feeding stuff manufacturer with adequate apparatus. The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tylosin should be adjusted accordingly. Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. Bodyweight should be evaluated accurately to avoid under dosing.

Mode of Administration

Administered orally via animal feed.

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.

Warnings and Precautions

Warnings for each target species:

None.

Special precautions for use in animals:

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.

Special precautions for person administering the products:

Tylosin may induce irritation. Macrolides, such a 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 conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143. 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.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. iii. Other precautions: None

Interactions 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.

Adverse 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(s)

Meat : Pig: Zero days. Broilers and pullets: 1 day.

Do not use in laying hens producing eggs for human consumption.

Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after opening and dilution: 24 hours.

Allowable Maximum Residual Limit (MRL)

Muscle, Liver, kidney, Skin+fat, (Pigs & Chickens)= 100 µg/kg, eggs (Chickens) = 300 µg/kg [Ref. CODEX 2012]

Storage Conditions

Store in tightly-closed original container, in a dry place below 30°C. Keep away from children. Jauhkan ubat dari kanak-kanak.

Disposal of containers :
Empty bags can be safely disposed in trash according to local government regulations.
Packaging
25kg in Low-density polyethylene plastic / polypropylene lined paper bag.
Name and Address of manufacturer
Life Biopharma Sdn. Bhd. (546163-D)
No. 250-251, Jalan Industri Galla 13, Kawasan Perindustrian Galla, 70200 Seremban, Negeri Sembilan, Malaysia.
Date of Revision of Package Insert
2016-05-23