ELANCO™ **AF0472**

[Pr]Pulmotil[TM] Premix
tilmicosin
FOR VETERINARY USE ONLY
ANTIBIOTIC

Net Weight 10 kg
DIN 02240124

PREMIX

FOR USE IN SWINE, FEEDLOT CATTLE AND RABBIT FEEDS ONLY

INDICATIONS:

1. As an aid in reducing the severity of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* when fed to pigs approximately 7 days prior to anticipated disease outbreak.[1]
2. As an aid in reducing the severity of porcine polyserositis and arthritis associated with *Haemophilus parasuis* (Glasser's Disease) when fed to pigs approximately 7 days prior to anticipated outbreak.[1]
3. For the reduction of bovine respiratory disease (BRD) morbidity associated with *Mannheimia haemolytica, Pasteurella multocida* and/or *Histophilus somni* in groups of feedlot beef cattle experiencing an outbreak of BRD.[2]
4. For the reduction in severity of respiratory disease caused by *Pasteurella multocida* in rabbits.

   Note: To promote responsible use and limit the development of antimicrobial resistance, use Pulmotil Premix only under the following conditions:

   [1] In swine when factors associated with outbreaks of SRD or Glasser's Disease (such as herd health status, target pig population, herd management and environmental factors, etc.) have been carefully considered.

   [2] In feedlot beef cattle when:
   1) clinical BRD has been diagnosed in at least 10% of animals in the group to be treated; AND
   2) treatment is initiated within the first 45 days of arrival in the feedlot; AND
   3) medication is limited to one single period of 14 consecutive days of treatment.

IMPORTANT:

Must be thoroughly mixed in feeds before use.

ACTIVE DRUG INGREDIENT:

tilmicosin (as tilmicosin phosphate).....200 g per kilogram

PRODUCT LABEL PROFILE
PULMOTIL PREMIX – 10KG

MIXING DIRECTIONS:

Indication 1:
Thoroughly mix 1.0 kg Pulmotil Premix into 999 kg non-medicated swine feed (to provide 200 g tilmicosin activity per tonne in complete feed).

Indication 2:
Thoroughly mix 2.0 kg Pulmotil Premix into 998 kg non-medicated swine feed (to provide 400 g tilmicosin activity per tonne in complete feed).

Indication 3:
Pulmotil Premix should be blended into an intermediate mix (premix or supplement) and then mixed into the complete diet [total mixed ration (TMR)] to supply 12.5 mg tilmicosin per kg of body weight (BW). The following is the calculation to determine the concentration of tilmicosin in the complete feed and the intermediate mix.

1) Calculate the amount (mg) of tilmicosin activity required per head per day.
   - body weight (kg) X 12.5 mg/kg BW
2) Calculate the dry matter intake (DMI) in kg per head per day.
   - body weight (kg) X estimated DMI as a percent of BW
3) Calculate the concentration (mg/kg) in the complete diet (TMR).
   - amount (mg) of tilmicosin required per head per day divided by the DMI (kg)
4) Calculate the concentration of tilmicosin in the intermediate mix (mg/kg = g/tonne).
   - concentration in the complete diet (mg/kg) divided by the intended inclusion rate (%) of the intermediate mix in the complete diet
5) Calculate the amount of Pulmotil Premix (kg) to be added per tonne (1000 kg) of the intermediate mix.
   - concentration of tilmicosin (g/tonne) in the intermediate mix divided by the Pulmotil Premix concentration (200 g tilmicosin per kg)

An example: Body weight is 300 kg; Dry matter intake as a percent of body weight is 2%; Intermediate premix or supplement is to be incorporated in the complete feed at 4% of dry matter.

1) 300 kg X 12.5 mg/kg = 3750 mg tilmicosin per head per day
2) 300 kg X 2% (or 300 x 0.02) = 6 kg dry matter intake per head per day
3) 3750 mg tilmicosin per head per day divided by 6 kg DMI = 625 mg tilmicosin/kg DMI
4) 625 mg/kg divided by 4% inclusion (or 625 mg/kg divided by 0.04) = 15,625 mg/kg = 15,625 g/tonne tilmicosin in the intermediate mix
5) 15,625 g/tonne tilmicosin in the intermediate mix divided by 200 g tilmicosin per kg Pulmotil Premix = 78.125 kg/tonne

Indication 4:
Pulmotil Premix should be blended into an intermediate mix (premix or supplement) and then mixed into the complete diet [total mixed ration (TMR)] to supply 12.5 mg tilmicosin per kg of body weight (BW), equivalent to 200 ppm in the feed, for 7 days. This is achieved by the incorporation of 1 kg Pulmotil Premix per tonne of feed.

PRODUCT LABEL PROFILE
PULMOTIL PREMIX – 10KG

FEEDING DIRECTIONS:

To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently and for the shortest duration required to achieve the desired clinical outcome.

Indication 1:
Feed at 200 g tilmicosin activity per tonne (1,000 kg) for a 21-day period, beginning approximately 7 days before an anticipated disease outbreak. Feed continuously as the sole ration.

Indication 2:
Feed at 400 g tilmicosin activity per tonne (1,000 kg) for a 21-day period, beginning approximately 7 days before an anticipated disease outbreak. Feed continuously as the sole ration.

Indication 3:
Feed at the appropriate concentration in medicated feed to target 12.5 mg/kg body weight/head/day for a 14-day period. Feed continuously in the complete diet (total mixed ration) of cattle.

Indication 4:
Feed at the appropriate concentration in medicated feed to target 12.5 mg/kg body weight/head/day for a 7-day period. Feed continuously as the sole ration.

CONTRAINDICATIONS:

1. Do not use in animals hypersensitive to tilmicosin.
2. Tilmicosin is known to be toxic for horses. Do not allow horses or other equines access to feeds containing tilmicosin.

CAUTIONS:

1. The safety of tilmicosin has not been established in boars used for breeding.
2. The effects of Pulmotil Premix on bovine reproductive performance, pregnancy and lactation have not been determined.
3. The effects of Pulmotil Premix on rabbit reproductive performance, pregnancy and lactation have not been determined.
4. The safety of Pulmotil Premix in pre-ruminant calves has not been established.
5. Do not use in any feed (supplement, concentrate, or complete feed) containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

WARNINGS:

1. Treated animals must not be slaughtered for use in food for at least 14 days for pigs, 28 days for cattle, and 4 days for rabbits after the latest treatment with this drug.
2. Do not use in lactating dairy cattle.
3. To limit the development of antimicrobial resistance, Pulmotil Premix should only be used in swine at high risk of developing swine respiratory disease (SRD) or Glasser's Disease and in feedlot beef cattle at high risk of developing bovine respiratory disease (BRD).

4. When mixing and handling Pulmotil Premix, avoid inhalation, oral exposure, and direct contact with skin or eyes.Use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention.
5. Keep out of reach of children.
6. To report adverse events in users or to obtain occupational safety information, call 1-800-265-5475.

STORE IN A COOL DRY PLACE

TAKE TIME/OBSERVE LABEL DIRECTIONS
LOGO

ELANCO
Division Eli Lilly Canada Inc.
150 Research Lane, Suite 120
Guelph, Ontario, Canada
N1G 4T2

Lot and Expiry are printed at time of filling.