



# Pr TILMICOSIN 200

*Tilmicosin (as tilmicosin phosphate) Premix 200 g/kg*

## FOR VETERINARY USE ONLY

Antibiotic

*Bio Agri Mix LP*

DIN 02461099

**FOR USE IN SWINE, FEEDLOT CATTLE AND RABBIT FEEDS ONLY - MUST BE THOROUGHLY MIXED IN FEEDS BEFORE USE.**

### ACTIVE INGREDIENT:

Tilmicosin (as tilmicosin phosphate).....200 g/kg

### 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 an anticipated disease outbreak.<sup>1</sup>
- 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 an anticipated disease outbreak.<sup>1</sup>
- 3) For reduction of bovine respiratory disease (BRD) morbidity associated with *Mannheimia haemolytica*, *Pasteurella multocida* and/or *Histophilus somni* in groups of feedlot cattle experiencing an outbreak of BRD.<sup>2</sup>
- 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 TILMICOSIN 200 premix only under the following conditions:

<sup>1</sup>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.

<sup>2</sup>In feedlot beef cattle when:

- a) clinical BRD has been diagnosed in at least 10% of animals in the group to be treated; AND
- b) treatment is initiated within the first 45 days of arrival in the feedlot; AND
- c) medication is limited to one single period of 14 consecutive days of treatment.

### DOSAGE AND ADMINISTRATION:

*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.*



**Supplemental Abbreviated New Drug Submission**  
**TILMICOSIN 200 (Premix for Swine, Cattle and Rabbits)**  
**BAM Proposed English Label Text**

### Swine

*Indication 1:* Feed at 200 g tilmicosin activity per tonne (1000 kg) for a 21 day period, beginning approximately 7 days before an anticipated outbreak. Feed continuously as the sole ration. To provide 200 g tilmicosin activity per tonne (1000 kg) in complete feed, thoroughly mix 1.0 kg of TILMICOSIN 200 into 999 kg non-medicated swine feed.

*Indication 2:* Feed at 400 g tilmicosin activity per tonne (1000 kg) for a 21 day period, beginning approximately 7 days before an anticipated outbreak. Feed continuously as the sole ration. To provide 400 g tilmicosin activity per tonne (1000 kg) in complete feed, thoroughly mix 2.0 kg TILMICOSIN 200 into 998 kg non-medicated swine feed.

### Beef Cattle

*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. TILMICOSIN 200 should be blended into an intermediate mix (premix or supplement) to supply 12.5 mg per kg of body weight (BW) and then mixed into the complete diet (total mixed ration [TMR]). Feed continuously in the complete diet (TMR) of cattle.

The following is the calculation to determine the concentration of tilmicosin in the complete feed and intermediate mix:

- I. Calculate the amount (mg) of tilmicosin activity required per head per day.
  - *Body weight (kg) x 12.5 mg/kg BW*
- II. Calculate the dry matter intake (DMI) in kg per head per day.
  - *Body weight (kg) x estimated DMI as a percent of BW*
- III. Calculate the concentration (mg/kg) in the complete diet (TMR)
  - *Amount (mg) of tilmicosin required per head per day divided by the DMI (kg)*
- IV. 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*
- V. Calculate the amount of TILMICOSIN 200 to be added per tonne (1000 kg) of the intermediate mix.
  - *Concentration of tilmicosin (g/tonne) in the intermediate mix divided by the TILMICOSIN 200 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.  $300 \text{ kg} \times 12.5 \text{ mg/kg} = 3750 \text{ mg tilmicosin per head per day}$
2.  $300 \text{ kg} \times 2\%$  (or  $300 \times 0.02$ ) = 6 kg dry matter intake per head per day
3.  $3750 \text{ mg tilmicosin per head per day} \div 6 \text{ kg DMI} = 625 \text{ mg tilmicosin/kg DMI}$
4.  $625 \text{ mg/kg} \div 4\%$  inclusion (or  $625 \text{ mg/kg} \div 0.04$ ) = 15,625 mg/kg or 15,625 g/tonne tilmicosin in the intermediate mix
5.  $15,625 \text{ g/tonne tilmicosin in the intermediate mix} \div 200 \text{ g tilmicosin per kg TILMICOSIN 200} = 78.125 \text{ kg/tonne}$

### Rabbits





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*Indication 4:* TILMICOSIN 200 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 feed for 7 days. This is achieved by the incorporation of 1 kg TILMICOSIN 200 per tonne of feed. 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 tilmicosin on bovine reproductive performance, pregnancy and lactation have not been determined.
- 3) The effects of tilmicosin on rabbit reproductive performance, pregnancy and lactation have not been determined.
- 4) The safety of tilmicosin 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 swine, 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, TILMICOSIN 200 should only be used in swine at high risk of developing SRD or Glasser's Disease and in feedlot beef cattle at high risk of developing BRD.
- 4) When mixing and handling TILMICOSIN 200, wear 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 effects in users or to obtain occupational safety information, call 1-800-265-1763.

**STORAGE:**

Store in a cool dry place below 30°C.

**NET WEIGHT:**

10 kg

**Bio Agri Mix LP**

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**CONTAINS  
ANTIMICROBIAL  
USE RESPONSIBLY**  
**CONTIENT UN  
ANTIMICROBIEN  
UTILISEZ DE FAÇON RESPONSABLE**



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**LOT:**

**EXP:**