



Veterinary Use Only

Pneumostop Tilmicosin 25% w/v Oral Solution

1. Brand or Product Name / Name and Strength of Active Substance(s)

Pneumostop Tilmicosin 25% w/v Oral Solution
Each liter contains: Tilmicosin (as tilmicosin phosphate) 250g

2. Product Description : Yellow to brown liquid solution

3. Pharmacodynamics/Pharmacokinetics/Environmental Properties

Pharmacodynamics :

Tilmicosin is a semi-synthetic antibiotic of the macrolide group, and is believed to affect bacterial protein synthesis through binding to 50S ribosomal subunits and inhibiting peptide formation. It is bacteriostatic but at high concentrations it may be bactericidal.

Tilmicosin has an in-vitro antibacterial spectrum that is predominantly Gram-positive with activity against certain Gram-negative micro-organisms. Activity against several mycoplasma species has also been demonstrated. Cross resistance between tilmicosin and other macrolide antibiotics has been observed.

Pharmacokinetics :

When administered orally to chickens and pigs with drinking water, tilmicosin is absorbed and moves rapidly out of the serum into areas of low pH. This results in very low serum concentrations, but detectable levels of tilmicosin are found in lung tissue as early as 6 hours after starting the treatment. In chicken, tilmicosin is also detected in pooled air sac tissue as early as 6 hours after starting the treatment. It is also known that tilmicosin is concentrated in alveolar macrophages of swine.

4. Indication

Pigs : For the treatment and prevention of respiratory disease in pig herds, associated with *Mycoplasma hyopneumoniae*, *Pasteurella multocida*, *Actinobacillus pleuropneumoniae*

Chickens: For the treatment and prevention of respiratory disease in chicken flocks, associated with *Mycoplasma gallisepticum* and *M. synoviae*

5. Recommended Dosage / Mode of Administration

Oral: via drinking water

- **Pigs :** 15–20mg tilmicosin per kg body weight for 5 days
(6–8mL of product for 100kg body weight corresponding to 80mL of Pneumostop per 100 litres of drinking water for 5 days)
- **Chickens :** 15–20mg tilmicosin per kg body weight for 3 days
(6–8mL of product for 100kg body weight corresponding to 30mL of Pneumostop per 100 litres of drinking water for 3 days)

6. Contraindications

- Hypersensitivity to tilmicosin or to any of the excipients.
- Concurrent administration of other macrolides or lincosamides.
- Parenteral administration, only for oral use.
- Administration to poultry producing eggs for human consumption or to animals intended for breeding purposes.

7. Warnings and Precautions

- Read full directions before use.
- Do not use in layers producing eggs for human consumption.
- Do not use in pregnant and breeding pigs.
- Keep the dosage and administration on label.
- Use by veterinarian's indication, and veterinary use only.
- Do not use for human.
- Use only for the designated animal on label.
- Keep out of reach of children/ Jauhkan ubat daripada kanak-kanak.

8. Interactions with Other Medicaments

This veterinary medicinal product must not be mixed with other products.

9. Statement on usage during pregnancy and lactation

This veterinary medicinal product must not be used during pregnancy and lactation.
Do not use in laying birds producing eggs for human consumption.

10. Adverse Effects/Undesirable Effects

If suspected adverse reactions occur, treatment should be discontinued and to inform veterinarian / local authority.

11. Overdose and Treatment

No symptoms of overdose have been seen in chickens given drinking water containing levels of tilmicosin up to 375mg/litre for 5 days. Pigs drink less water when a dose of 300 to 400 mg/litre (equivalent to 22.5–40mg/kg bodyweight or 1.5–2 times the recommended concentration) is administered. This may lead to dehydration and access to untreated drinking water may be required.

12. Withdrawal Period(s)

Pigs - 14 days
Chickens - 12 days

13. Shelf life (after first opening of container or after dilution)

24 hours

14. Storage Condition

Store in a room temperature below 30°C.
Protect from light.

15. Dosage Forms and packaging available

960mL

16. Name and Address of manufacturer/marketing authorization holder

Nutri Pharmax Sdn Bhd
6, Lorong Serunai 1, Valdor Sungai Bakap, 14200 Sungai Jawi, Pulau Pinang, Malaysia.

17. Date of Revision of Package Insert : 12 JUL 2019

Manufactured by
 **KBNP, INC.**
235-9 Chusaro, Sinam, Yesan,
Chungnam, Korea

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