

Indications

For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Use Program

For use in Swine feeds only.

Important: Do not feed undiluted. Must be thoroughly mixed into feeds before use.

Mixing Directions: Thoroughly mix Pulmotil 18 with feed to provide a complete Type C Medicated Feed containing 181 to 363 grams of tilmicosin per ton. Do not use in concentrates or in feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

Amount of Pulmotil 18 to add per ton of complete feed	Resulting Pulmotil concentration per ton of complete feed
10 lbs	181 g
15 lbs	272 g
20 lbs	363 g

Ingredients: Rice Hulls, Calcium Carbonate, Distillers Dried Grains with Solubles, and Mineral Oil.

Guaranteed Analysis:

Crude Protein, Minimum	· · · · · 4.6%
Crude Fat, Minimum	· · · · · 1.3%
Crude Fiber, Maximum	· · · · · 32.2%
Calcium, Minimum	· · · · · 4.4%
Calcium, Maximum	· · · · · 5.4%
Phosphorous, Minimum	· · · · · 0.3%

This product has been formulated to contain at least 25% nutrient content.

Key Points

1. Activity against key swine respiratory pathogens (*Actinobacillus pleuropneumoniae* and *Pasteurella multocida*).
2. Enhances the pig's own natural defense mechanisms by concentrating in alveolar macrophages.
3. In clinical field trials, none of the pigs receiving Pulmotil died of pneumonia; 14 out of 383 nonmedicated control pigs died, resulting in greater than 3.5 % mortality.
4. Trials also show that Pulmotil treated animals gained 38% more body weight and their feed efficiency was 15% better than non-treated control animals when pneumonia was present in the herd.
5. Consumption of up to 10 times the highest recommended dose of Pulmotil in the diet of swine for up to 21 days had no adverse effect on pig growth, health, or performance.
6. Can be fed only with a veterinary feed directive (VFD).

Important: For additional information on Pulmotil, see the reverse side of this sheet.

Pulmotil[®] 18

tilmicosin phosphate

Product number AF 0463

Type B Medicated Feed

Category II Feed Additive Premix containing 18.1 Grams of Tilmicosin (as tilmicosin phosphate) Per Pound

FDA STATUS: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.

PACKAGE: 50-pound multi-wall, flat-bottom baler bag containing five 10-pound bags

STORAGE: Store in a cool, dry area.



ELANCO
ANIMAL HEALTH

TM

Pulmotil® 18 Premix for Swine

tilmicosin

Type B medicated feed

Do not feed undiluted

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Active Drug Ingredient: tilmicosin (as tilmicosin phosphate) 18.1 grams per pound (40 grams per kilogram)

Inert ingredients: ground corn cobs

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin phosphate is produced semi-synthetically and is in the macrolide class of antibiotics. Each pound of Type B medicated feed contains 18.1 grams of tilmicosin base as tilmicosin phosphate adsorbed onto ground corn cobs.

Activity: Tilmicosin has an *in vitro** antibacterial spectrum that is predominately Gram-positive with activity against certain Gram-negative microorganisms. Activity against several mycoplasma species has also been detected.

<u>Microorganism</u>	<u>MIC</u> ($\mu\text{g/ml}$)
<i>Actinobacillus pleuropneumoniae</i>	16
<i>Pasteurella multocida</i>	8
<i>Mycoplasma hyopneumoniae</i>	0.5
<i>Escherichia coli</i>	>64
<i>Salmonella choleraesuis</i>	>64
<i>Streptococcus suis</i>	>64

*The clinical significance of these *in vitro* data has not been demonstrated.

Pharmacology: Oral dosing of tilmicosin phosphate at 181 to 363 grams per ton of feed results in serum tilmicosin levels which do not correlate with efficacy. Lung concentrations of tilmicosin are significantly higher than serum. Lung levels are achieved within 2 days after beginning feeding and plateau by 4 days. Swine alveolar macrophages have been shown *in vitro* to concentrate large amounts of tilmicosin; these cells may serve as an important reservoir in lung tissue.

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Caution: Do not allow horses or other equines access to feeds containing tilmicosin. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes.

Warning: Feeds containing Pulmotil must be Withdrawn 7 days prior to slaughter.

Warning: Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling Pulmotil 18 should use protective clothing, impervious gloves, goggles, and a NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Material Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a Material Safety Data Sheet, call 1-800-428-4441.

Adverse Drug Reactions: No adverse toxicological effects were observed in swine given rations containing 2000 ppm tilmicosin for 42 days and 4000 ppm for 21 days.

For Technical Service Call: 1-800-428-4441

Toxicology: The cardiovascular system is the target of toxicity in laboratory and domestic animals given tilmicosin by oral or parenteral routes. Primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy). Given orally, the median lethal dose is 800 milligrams per kilogram of body weight in fasted rats and 2250 mg/kg in non-fasted rats. No compound-related lesions were found at necropsy. Results of genetic toxicology studies were all negative. Results of teratology and reproduction studies in rats were all negative. The no effect level in dogs after daily oral doses for up to one year is 4 mg/kg of body weight.

IMPORTANT: Must be thoroughly mixed in feeds before use.

Feeding Directions: Pulmotil is to be fed continuously at 181 grams to 363 grams tilmicosin per ton (200 ppm to 400 ppm) of Type C medicated feed as the sole ration for a 21-day period, beginning approximately 7 days before an anticipated disease outbreak.

Mixing: Read bag label carefully for mixing directions. Do not use in any feed containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

