PULMOTIL 90- tilmicosin phosphate granule
Elanco US Inc.

Elanco™

AF0472

Pulmotil™ 90

Net Weight:

10 kg (22.0 lb)

Tilmicosin

Type A Medicated Article

CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

For Use in Swine and Cattle Feeds Only.

Do not feed undiluted.

Active Drug Ingredient: Tilmicosin (as tilmicosin phosphate) 90.7 g per lb (200 g per kg)

Inert Ingredients: Ground corncobs.

Description:

Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (0.44 lbs) of tilmicosin adsorbed onto ground corncobs.

Indications:

Swine: For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

Cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group.

Feeding Directions:

Swine: Tilmicosin is to be fed continuously at 181 grams to 363 grams 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.

Cattle: Tilmicosin is to be fed continuously for a single, 14 day period at 568 grams to 757 grams (626 ppm to 834 ppm) per ton on a 100% dry matter basis of Type C medicated feed as the sole ration to provide 12.5 mg/kg of body weight/day.

IMPORTANT: Must be thoroughly mixed in swine or cattle feeds before use.

Mixing Directions:

For Incorporation into Swine Feeds: Thoroughly mix Pulmotil Type A medicated article with feed to provide a Type B medicated feed containing up to 36,300 grams tilmicosin per ton or to provide a complete Type C medicated feed containing 181 to 363 g tilmicosin per ton. Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

Starting concentration of Pulmotil 90 Type A Medicated Article[a]	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type B Medicated Feed	
grams per pound	pounds	grams per ton	grams per pound
90.7	400	36,300	18.1
	300	27,200	13.6
	200	18,100	9.1

Starting concentration of Pulmotil 90 Type A Medicated Article[a]	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed
grams per pound	pounds	grams per ton
90.7	4	363
	3	272
	2	181

[a]Pulmotil 90 contains 90.7 g tilmicosin phosphate per pound

For Incorporation into Cattle Feeds: Thoroughly mix Pulmotil Type A medicated article with feed to provide a Type B medicated feed containing up to 36,300 grams tilmicosin per ton on a 100% dry matter basis or to provide a complete Type C medicated feed containing 568 to 757 g tilmicosin per ton on a 100% dry matter basis. Complete Type C medicated feeds should not be pelleted. Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.

Starting concentration of Pulmotil 90 Type A Medicated Article[a]	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type B Medicated Feed[b]	
grams per pound	pounds	grams per ton	grams per pound
	400	36,300	18.1

90.7	200	18,100	9.1
	100	9,070	4.5

Starting concentration of Pulmotil 90 Type A Medicated Article[a]	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed[b]
grams per pound	pounds	grams per ton
90.7	8.35	757
	6.26	568

[a]Pulmotil 90 contains 90.7 g tilmicosin phosphate per pound
[b]100% dry matter basis

CAUTION:

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

To assure both food safety and responsible use in cattle, the treatment of cattle with this medicated feed is required to be initiated within the first 45 days of the production period. The treatment should not occur concurrent with or following administration of an injectable macrolide, or within 3 days following administration of a non-macrolide injectable BRD therapy.

Swine: Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before re-initiating a further course of therapy with an appropriate antimicrobial. Veterinary Feed Directive (VFD) expiration date for swine must not exceed 90 days from the time of issuance. VFDs for tilmicosin phosphate shall not be refilled.

Cattle: Use only in cattle fed in confinement for slaughter. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy. The expiration date for a tilmicosin Veterinary Feed Directive (VFD) for cattle must not exceed 45 days from the time of issuance. VFDs for tilmicosin phosphate shall not be refilled.

WARNINGS:

RESIDUE WARNING: Swine: Swine intended for human consumption must not be slaughtered within 7 days of the last treatment of this drug product.

RESIDUE WARNING: Cattle: Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.

This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves.

User Safety Warnings: Avoid inhalation, oral exposure and direct contact with skin or eyes. Operators mixing and handling Pulmotil 90 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 Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a Safety Data Sheet, call 1-800-428-4441.

Clinical Pharmacology: Oral dosing of tilmicosin phosphate to swine at 181 to 363 g/ton of feed results in serum tilmicosin levels, which do not correlate with efficacy. Lung concentrations of tilmicosin are significantly higher than serum. Following 7 consecutive days of administering tilmicosin-medicated feeds to swine, the concentration of tilmicosin in respiratory tissues, phagocytic cells, and nasal secretions was significantly higher than that of plasma or serum. Lung levels are achieved within 2 days after beginning feeding and plateau by 4 days. Using *in-vitro* incubation techniques, the ratio of intracellular to extracellular concentrations of tilmicosin for neutrophils, monocyte-macrophages and alveolar macrophages were 69, 19 and 17, respectively, after four hours of incubation. Although lower levels of accumulation were observed *in-vivo*, swine alveolar macrophages have been shown *in-vitro* and *in-vivo* to concentrate large amounts of tilmicosin; these cells may be important for in-vivo distribution of the drug and may serve as an important reservoir for tilmicosin in lung tissue.

Oral dosing of tilmicosin phosphate to cattle to target a dose of 12.5 mg/kg body weight resulted in serum tilmicosin concentrations above the analytical limit of quantification (0.5 ng/mL) within 12 hours following treatment administration. The relationship of serum tilmicosin concentration to lung tilmicosin concentration has not been determined following oral administration of tilmicosin.

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 mg/kg 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. Tilmicosin was included in the diet of 18 adult horses for a period of 14 days at dose levels of 400, 1200 and 2000 ppm. Some horses at both the low and high dose levels demonstrated gastrointestinal disturbance with more severe colic evident at the higher levels. One horse died after consuming the 2000 ppm diet. A study was conducted in cattle administered oral tilmicosin at 12.5, 25.0 or 37.5 mg/kg for 42 days or administered 12.5 mg/kg of oral tilmicosin for 14 days followed by 20 mg/kg injection of tilmicosin or saline (volume equivalent). Cardiac lesions observed (one animal in the 12.5 mg/kg for 42 days treatment group; one animal in the 12.5 mg/kg for 14 days followed by tilmicosin injection treatment group) were not considered clinically significant as no other abnormalities were seen and the affected animals were clinically normal.

To report adverse effects, access medical information or obtain additional product information, call 1-800-428-4441.

Storage Information: Store at less than or equal to 25°C (77°F). Excursions to 40°C

(104°F) are acceptable. Avoid excessive moisture.

Not to be used after the date printed on the bag.

Restricted Drug (California) - Use Only as Directed

Approved by FDA under NADA # 141-064

Manufactured For: Elanco US Inc, Greenfield, IN 46140, USA

TAKE TIME TO

OBSERVE LABEL DIRECTIONS

BG280428X

Principal Display Panel – 22 lb Bag Label

Elanco™ AF0472

Pulmotil™ ***90***

Net Weight:
10 kg (22.0 lb)

Tilmicosin

Elanco™

AF0472

Pulmotil™ 90

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Active Drug Ingredient: Tilmicosin (as tilmicosin phosphate) 90.7 g per lb (200 g per kg)

Inert Ingredients: Ground corncobs.

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grams per pound	pounds	grams per ton	grams per pound
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	200	18,100	9.1
	100	9,070	4.5
Starting concentration of Pulmotil 90 Type A Medicated Article[a]	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed[b]	
grams per pound	pounds	grams per ton	
	8.25	757	

90.7	6.26	568

[a]Pulmotil 90 contains 90.7 g tilmicosin phosphate per pound [b]100% dry matter basis

CAUTION:

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

To assure both food safety and responsible use in cattle, the treatment of cattle with this medicated feed is required to be initiated within the first 45 days of the production period. The treatment should not occur concurrent with or following administration of an injectable macrolide, or within 3 days following administration of a non-macrolide injectable BRD therapy.

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This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk.

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Restricted Drug (California) - Use Only as Directed

Approved by FDA under NADA # 141-064

Manufactured For: Elanco US Inc, Greenfield, IN 46140, USA

TAKE TIME TO

OBSERVE LABEL DIRECTIONS

YL280428X

Elanco™

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Restricted Drug (California) - Use Only as Directed

Approved by FDA under NADA # 141-064

Manufactured For: Elanco US Inc, Greenfield, IN 46140, USA

Pulmotil, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

BG280428X

PULMOTIL 90

tilmicosin phosphate granule

Product Information			
Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	**Item Code (Source)**	NDC:58198-0472
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
tilmicosin phosphate (UNII: SMH7U1S683) (tilmicosin - UNII:XL4103X2E3)	tilmicosin phosphate	200 g in 1 kg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58198-0472-9	10 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141064	10/18/2012	

Labeler - Elanco US Inc. (966985624)

Establishment

Name	Address	ID/FEI	Business Operations
Evonik Corporation		130890994	API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
TriRx Speke Limited		228138655	MANUFACTURE, PACK, LABEL

Revised: 7/2022 Elanco US Inc.