

TILMOVET 90 TYPE A MEDICATED ARTICLE- tilmicosin phosphate powder
Huvepharma, Inc.

Tilmovet® 90 **LB496v8Til90mp20-USA0421**
(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 veterinary.

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: Corncobs, macrogolglycerol ricinoleate.

Description: Tilmovet® (tilmicosin) 90 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 nonlactating 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 Tilmovet 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.

For Incorporation into Cattle Feeds: Thoroughly mix Tilmovet 90 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.

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Net weight:20 kg (44.0 lb)

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 nonmacrolide 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 Tilmovet 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 1-877-426-7765.

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 suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Storage Information: Store at room temperature 20 – 25 °C (68 – 77 °F).
Excursions permitted to 30°C (86°F).
Avoid moisture and excessive heat 40°C (104°F).

Not to be used after the date printed on the bag

Not for Use in Humans

Restricted Drug (California) - Use Only as Directed

Approved by FDA under ANADA # 200-509

Manufactured For:

Huvepharma, Inc., Peachtree City, GA 30269, USA

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Rev. 03-2022

TILMOVET 90 TYPE A MEDICATED ARTICLE				
tilmicosin phosphate powder				
Product Information				
Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG		Item Code (Source)	NDC:23243-2395
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
TILMICOSIN PHOSPHATE (UNII: SMH7U1S683) (TILMICOSIN - UNII:XL4103X2E3)			TILMICOSIN	200 g in 1 kg
Inactive Ingredients				
Ingredient Name			Strength	
corn cob (UNII: XXP8V4H4NY)				
castor oil (UNII: D5340Y2I9G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-2395-4	20 kg in 1 BAG		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANADA	ANADA200509		07/31/2013	

Labeler - Huvepharma, Inc. (619153559)

Registrant - Huvepharma EOOD (552691651)

Establishment

Name	Address	ID/FEI	Business Operations
Biovet-AD		645015512	medicated animal feed manufacture, manufacture, analysis, pack, label, api manufacture

Revised: 6/2022

Huvepharma, Inc.