TILMOVET 90- tilmicosin phosphate powder
Huvepharma, Inc.

Tilmovet 90 Type A Medicated Article

tilmicosin

Tilmovet 90 Type A Medicated Article

tilmicosin Net weight: 10 kg (22.0 lb)

Do Not Feed Undiluted

CAUTION: 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.

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

Inert Ingredients: Corncobs, macrogolglycerol ricinoleate.

Description: Timovet 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 and macrogolglycerol ricinoleate.

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

Feeding Directions: 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.

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

Mixing Directions: 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.

Starting concentration of Tilmovet 90 Type A Medicated Article	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	9.05
Starting concentration of Tilmovet 90 Type A Medicated Article	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	

[1]Tilmovet 90 contains 90.7 g tilmicosin phosphate per pound

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.

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.

WARNINGS

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

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 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 1-877-462-7765.

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 higher than serum. Following seven 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.

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.

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

To report adverse effects, access medical information, or obtain additional product information, call 1-877-426-7765.

Storage Information: Store at room temperature 25^0C (77^0F). Excursions permitted to 30^0C (86^0F).

Avoid moisture and excessive heat 40^0C (104^0F)

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

Restricted Drug (California) - Use Only as Directed

ANADA 200-509, Approved by FDA

Manufactured for:

Huvepharma AD

3a Nikolay Haytov Str.

1113 Sofia, Bulgaria

Distributed by:

Huvepharma Inc.

525 Westpark Drive, Suite 230

Peachtree City, GA 30269

Take time

Tilmicosin 90 label image

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Restricted Drug (California) – Use Only as Directed.
ANADA 200-509, Approved by FDA
Manufactured for:
Huvepharma AD
3a Nikolay Haytov Str.
1113 Sofia, Bulgaria

TAKE TIME
OBSERVE LABEL DIRECTIONS

Distributed by:
Huvepharma Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

LOT 00000000000
EXP 0000000

TYPE A MEDICATED ARTICLE
PIGS

22
PAP

TILMOVET 90

tilmicosin phosphate powder

Product Information

	VFD TYPE A MEDICATED ARTICLE ANIMAL	Item Code	NDC:33242

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-2395-1	1.0 kg in 1 BAG		
2	NDC:23243-2395-2	5 kg in 1 BAG		
3	NDC:23243-2395-3	10 kg in 1 BAG		
4	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, AD (552691651)

Establishment

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

Revised: 10/2013 Huvepharma, Inc.