

BILOVET- tylosin tartrate powder, for solution
Bimeda, Inc.

BiloVet®
(tylosin tartrate)
Soluble Powder

For oral use in chickens, turkeys, swine, and honey bees
Macrolide Antibiotic

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Indications:

Chickens: For the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens. As an aid in the treatment of chronic respiratory disease (**CRD**) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens.

Turkeys: For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum*.

Swine: For the treatment and control of swine dysentery (**SD**) associated with *Brachyspira hyodysenteriae*. For the treatment and control of SD associated with *Brachyspira hyodysenteriae* when followed immediately by tylosin phosphate Type A medicated article in feed. For the control of porcine proliferative enteropathies (**PPE**, ileitis) associated with *Lawsonia intracellularis* when followed immediately by tylosin phosphate Type A medicated article in feed.

Honey Bees: For the control of American Foulbrood (*Paenibacillus larvae*).

Ingredient: Tylosin (as tylosin tartrate) ... 100 g

Dosage and Administration

Dosages:

Chickens:

NE indication: 851 to 1,419 mg/gallon (225 to 375 ppm) in drinking water.

CRD indications: 2,000 mg/gallon (528 ppm) in drinking water.

Turkeys: 2,000 mg/gallon (528 ppm) in drinking water.

Swine: 250 mg/gallon (66 ppm) in drinking water.

Honey Bees: 200 mg/colony in confectioners/powdered sugar.

Mixing Directions for Medicated Drinking Water:

Always add the water to the powder. Do not pour the powder into the water. Prepare a fresh BiloVet solution every three days. When mixing and handling tylosin, use protective clothing and impervious gloves. If using a water medicating pump see table below, otherwise mix as follows: To assure thorough dissolution, first place the contents of one jar/packet in a mixing container and add one gallon of water (3785 mL) to the powder to make a concentrated solution.

To make medicated drinking water containing 250 mg/gallon (66 ppm), mix this

concentrated solution with water to make 400 gallons (1514 liters) of medicated drinking water.

To make medicated drinking water containing 851 to 1,419 mg/gallon (225 to 375 ppm), mix this concentrated solution with water to make from 117 gallons + 51 ounces (444 liters) to 70 gallons + 64 ounces (267 liters) of medicated drinking water, respectively.

To make medicated drinking water containing 2,000 mg/gallon (528 ppm), mix this concentrated solution with water to make 50 gallons (189 liters) of medicated drinking water.

Mixing Directions for Water Medicating Pump (1:128 <u>inclusion</u>):		
Desired Concentration in Drinking Water	Jars/Packets of <u>Bilovet</u>	Volume of water to make Stock Solution
250 mg/gallon (66 ppm)	1	3 gallons + 13 ounces
851 mg/gallon (225 ppm)	5	4 gallons + 77 ounces
1,419 mg/gallon (375 ppm)	9	5 gallons + 0 ounces
2,000 mg/gallon (528 ppm)	10	3 gallons + 115 ounces

*This table applies only if the water medicating pump is set to deliver 1 ounce of stock solution per gallon of drinking water.

Mixing Directions for use in Honey Bees: Mix 200 mg tylosin in 20 g confectioners/powdered sugar. Use immediately.

Directions for Use

Chickens: NE indication: Administer medicated drinking water for a single five day period in broiler chickens. To assure all birds receive the intended medication, only medicated water should be available. These practices should be followed to assure both food safety and responsible antimicrobial drug use in chickens: 1) Use in flocks exhibiting signs of a necrotic enteritis outbreak, for example, increased mortality and lesions characteristic of necrotic enteritis upon necropsy; 2) Administer the full dose and dosing regimen once medication initiated; 3) Use of BiloVet or another macrolide is not advised if additional therapy is needed beyond the original course of medication.

Chickens: CRD indications: Administer medicated drinking water for three days; however, medicated water may be administered for one to five days depending upon severity of infection. Treated chickens must consume enough medicated water to provide 50 mg per pound of body weight per day. Only medicated water should be available to the birds.

Turkeys: Administer medicated drinking water for three days; however, medicated water may be administered for two to five days depending upon severity of infection. Treated turkeys must consume enough medicated water to provide 60 mg per pound of body weight per day. Only medicated water should be available to the birds.

Swine: SD indication: Administer medicated drinking water for 3 to 10 days, depending upon severity of infection. Alternatively, administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g of tylosin per ton of complete feed (Type C medicated feed manufactured from tylosin phosphate Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with BiloVet. **PPE indication:** Administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g of tylosin per ton of complete feed (Type C medicated feed

manufactured from tylosin phosphate Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with BiloVet.

Honey Bee Colonies: Administer three treatments of medicated confectioners sugar once weekly for 3 weeks. The 200 mg dose is applied (dusted) over the top bars of the brood chamber.

Warnings

User Safety Warnings:

Not for Human Use. Keep out of Reach of Children. Avoid contact with human skin. Exposure to tylosin may cause a rash.

Residue Warnings: Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption. **Turkeys** must not be slaughtered for food within five days after treatment. Do not use in layers producing eggs for human consumption. **Swine** must not be slaughtered for food within 48 hours after treatment. **Honey Bees:** The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks prior to main honey flow.

Store at or below 25°C (77°F). Excursions permitted to 40°C (104°F). Avoid Moisture.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Approved by FDA under ANADA # 200-455

BiloVet[®]

(tylosin tartrate)

Soluble Powder

For oral use in chickens, turkeys, swine, and honey bees

Macrolide Antibiotic

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Indications

Chickens: For the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens. As an aid in the treatment of chronic respiratory disease (**CRD**) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens.

Turkeys: For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum*.

Swine: For the treatment and control of swine dysentery (**SD**) associated with *Brachyspira hyodysenteriae*. For the treatment and control of SD associated with *Brachyspira hyodysenteriae* when followed immediately by tylosin phosphate Type A medicated article in feed. For the control of porcine proliferative enteropathies (**PPE**, ileitis) associated with *Lawsonia intracellularis* when followed immediately by tylosin phosphate Type A medicated article in feed.

Honey Bees: For the control of American Foulbrood (*Paenibacillus larvae*).

Warnings

User Safety Warnings: Not for Human Use. Keep Out of Reach of Children. Avoid contact with human skin. Exposure to tylosin may cause a rash.

Restricted Drug (California) - Use Only as Directed

Approved by FDA under ANADA # 200-455



Equivalent to
100 g (3.53 oz) tylosin base

Manufactured for:
Bimeda, Inc.
Le Sueur, MN 56058
www.bimeda.com

BiloVet[®] (tylosin tartrate) Soluble Powder

For oral use in all species: turkeys, swine, and honey bees

Ingredient:

Tylosin (as tylosin tartrate) 100 g

Dosage and Administration

Dosages:

Chickens:

NE Indication: 40 to 49 mg/avian (1.5 to 1.75 ppm) in drinking water

CFD Indications: 2,000 mg/gallon (529 ppm) in drinking water

Turkeys: 2,000 mg/gallon (529 ppm) in drinking water

Swine: 275 mg/calf (14 ppm) in drinking water

Honey Bees: 200 mg/colony in perfect comb or frame sugar

Mixing Directions for Medicated Drinking Water:

Always add the water to the powder. When pouring the powder into the container, wear a face shield and eye protection. When mixing and handling, wear eye protection and impervious gloves. Flush a water-medication pump, syringe, or other device before and after use.

To make a 100% solution: Dissolve the contents of one packet in a 1-gallon container and add one gallon of water (50% of total volume) to make a concentrated solution. Combine medicated drinking water containing 450 mg/gallon (90 ppm) of this concentrated solution with water to make 500 gallons (1514 liters) of medicated drinking water. To make a 10% solution: Dissolve the contents of one packet in 1.499 gallons (57.1 liters) of water (22.5 to 23.5 ppm), mix this concentrated solution with water to make 100 gallons (302.8 liters) of medicated drinking water, reconstitute. To make a 1% solution: Dissolve the contents of one packet in 14.99 gallons (57.1 liters) of water (2.25 to 2.35 ppm), mix this concentrated solution with water to make 1000 gallons (3028 liters) of medicated drinking water, reconstitute. To make a 0.5% solution: Dissolve the contents of one packet in 29.98 gallons (114.2 liters) of water (1.125 to 1.175 ppm) in the concentrated solution and water to make 2000 gallons (5945 liters) of medicated drinking water, reconstitute.

Mixing Directions for Water Mediating Pump (1:128 Inclusion):

Desired Concentration in Drinking Water	Articles of BiloVet	Volume of Water to Make Stock Solution
200 mg/gallon (52.9 ppm)	1	2 gallons = 16 ounces
450 mg/gallon (112.5 ppm)	5	4 gallons = 27 ounces
1,499 mg/gallon (374.75 ppm)	9	5 gallons + 1 ounce
2,000 mg/gallon (529 ppm)	10	3 gallons + 11.5 ounces

*This table applies only to water-medication pumps set to deliver one ounce of stock solution per gallon of drinking water.

Mixing Directions for use in Honey Bees: Mix 200 mg tylosin in 200 cc of water or one spoonful of sugar for minimal delay.

Directions for Use

Chickens: **NE Indication:** Administer the stock drinking water for a single five-day period in broiler chickens. To assure all birds receive the needed medication, only medicated water should be available. These procedures should be followed to ensure proper food safety and responsible antibiotic use in chickens: 1) Use a flock of one age, sex, and breed; 2) Use a clean, dry, well-ventilated, and secure housing; 3) Use a clean, dry, well-ventilated, and secure housing; 4) Administer the full dose and finish regimen once the flock is clean; 5) Use BiloVet in another machine is not advised. If additional therapy is needed, beyond the original course of medication. **CFD Indications:** Administer medicated drinking water for 10 days, however, medication may be administered for up to 14 days depending upon severity of infection. Treated chickens must consume enough medicated water to provide 50 mg per pound of body weight per day. Only medicated water should be available to the birds.

Turkeys: Administer medicated drinking water for three days, however, medication may be administered for the full five days depending upon severity of infection. Treated turkeys must consume enough medicated water to provide 50 mg per pound of body weight per day. Only medicated water should be available to the birds.

Swine: **SD Indications:** Administer medicated drinking water for 10 to 14 days, depending upon severity of infection. Administer a 10% stock solution of medicated drinking water for 10 to 14 days, followed by 100% of water per day of complete herd health and hygiene. Administer a 10% stock solution of medicated drinking water for 10 to 14 days, followed by 100% of water per day of complete herd health and hygiene.

Honey Bee Colonies: Administer three treatments of medicated water over the course of 3 weeks. The 100% stock solution should be available to the bees for the first 10 days, followed by 10% of water per day of complete herd health and hygiene. Administer a 10% stock solution of medicated drinking water for 10 to 14 days, followed by 100% of water per day of complete herd health and hygiene.

Warnings: Administer three treatments of medicated water over the course of 3 weeks. The 100% stock solution should be available to the bees for the first 10 days, followed by 10% of water per day of complete herd health and hygiene.

Warnings:

User Safety/Warnings: Water-Human Use: Keep Out of Reach of Children. Avoid contact with human skin. Exposure to eyes may cause redness.

Residue/Warnings: Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption. Turkeys must not be slaughtered for food within 14 days after treatment. Do not use in layers producing eggs for human consumption. Swine must not be slaughtered for food within 14 days after treatment. Honey Bees: The drug should not be used in the spring or fall and should not be used by the bees before the main honey flow begins. It is not recommended for use in honey. Complete treatment at each brood and home in honey flow.

Storage: Store below 25°C (77°F). Excursions Permitted to 40°C (104°F). Avoid Moisture.

For product safety, efficacy, and quality information, please contact the Bayer Animal Health Division, P.O. Box 100, Kansas City, MO 64108. For additional information about BiloVet, please refer to the animal drug control data at 1-800-TD-4-2-25 or visit www.bayer.com/usa/animal.



BiloVet[®] is a registered trademark of Bimeda, Inc.
© 2011 Bimeda, Inc. All rights reserved.

BILOVET

tylosin tartrate powder, for solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:61133-5600
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TYLOSIN TARTRATE (UNII: 5P4625C51T) (TYLOSIN - UNII: YEF4JXN031)	TYLOSIN	100 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-5600-2	100 g in 1 PACKET		
2	NDC:61133-5600-1	100 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200455	05/15/2015	

Labeler - Bimeda, Inc. (060492923)**Registrant** - Bimeda, Inc. (060492923)

Revised: 3/2024

Bimeda, Inc.