

TYLOVET- tylosin tartrate powder, for solution
Huvepharma, Inc.

TYLOVET SOLUBLE

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 Tylovet Type A medicated article in feed. For the control of porcine proliferative enteropathies (**PPE**, ileitis) associated with *Lawsonia intracellularis* when followed immediately by Tylovet Type A medicated article in feed.

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

INGREDIENTS

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 Tylovet Soluble 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 pouch 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 inclusion)*:

Desired Concentration

Desired Concentration in Drinking water	Pouches of Tylovet Soluble	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.

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 is initiated; 3) Use of Tylovet Soluble or another macrolide is not advised if additional therapy is needed beyond the original course of medication. **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 tylosin per ton of complete feed (Type C medicated feed manufactured from Tylovet Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylovet Soluble. **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 Tylovet A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylovet Soluble.

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.

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.

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.

SAFETY INFORMATION

User Safety Warnings: Keep Out of Reach of Children. Avoid contact with human skin. Exposure to tylosin may cause a rash.

How supplied:

Tylovet® Soluble is supplied in pouches of laminated aluminum foil, 100 g of tylosin activity per pouch; or HDPE jars with PP cap with heat sealable coating, 100 g of tylosin activity per jar.

STORAGE**Storage:**

Store at Room Temperature, 25°C (77°F).

Excursions Permitted to 40°C/104°F. Avoid moisture.

TOP AND BOTTOM LABEL TEXT

Tylovet® Soluble
(Tylosin Tartrate)

Equivalent to 100 g (3.53 oz) tylosin base

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. For oral use in chickens, turkeys, swine, and honey bees

Macrolide Antibiotic, ANADA# 200-473, Approved by FDA Product 2220

Restricted Drug (California) - Use only as Directed

ANADA # 200-473, Approved by FDA

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

Manufactured for: Huvepharma Inc. Peachtree City, GA 30269 , Made in Bulgaria
Tylovet® is a registered trademark of Huvepharma EOOD

Lot: 0000000000 Exp. Date: 00.0000 Code: LB444v4-Tyl100-USA1017

POUCH LABEL IMAGE

The image shows a portion of a product label for Tylovet Soluble. On the left, there is a blue graphic of a curved branch with several small circular nodes. The main text is in black: "Tylovet® Soluble" in a large font, followed by "Tylosin Tartrate" in a slightly smaller font. Below this, it says "Equivalent to 100 g (3.53 oz) tylosin base" and "CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian." In blue text, it reads "For oral use in chickens, turkeys, swine, and honey bees." Below that, in black, it says "Macrolide Antibiotic, ANADA 200-473, approved by FDA" and "Product 2220". To the right of the main text is a circular logo with three wavy lines. Further to the right, there is a vertical blue bar with white text: "GRANULES FOR ORAL SOLUTION" and "Chickens, Turkeys, Swine and Honey Bees".

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Restricted Drug (California) - Use Only as Directed.

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Manufactured for: Huvepharma Inc.

Peachtree City, GA 30269, Made in Bulgaria

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Lot: 00000000000

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POUCH LABEL IMAGE 2

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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 tylosin per ton of complete feed (Type C medicated feed manufactured from Tylovet Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylovet Soluble. **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 Tylovet A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylovet Soluble.

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:

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How supplied:

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

TYLOVET

tylosin tartrate powder, for solution

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:23243-2220

Route of Administration	ORAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TYLOSIN TARTRATE (UNII: 5P4625C51T) (TYLOSIN - UNII: YEF4JXN031)	TYLOSIN	100 g in 3970 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-2220-1	100 in 1 CASE		
1		3790 mL in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200473	01/01/2011	

Labeler - Huvepharma, Inc. (619153559)

Establishment			
Name	Address	ID/FEI	Business Operations
Biovet Joint Stock Company		645015512	api manufacture, manufacture, analysis, pack, label