

TYLOSIN SOLUBLE POWDER- tylosin tartrate powder, for solution MWI/VetOne

**Tylosin Soluble Powder
(tylosin tartrate)**

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 Tylosin Soluble Powder 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 inclusion)*

| Desired Concentration in Drinking Water | Jars/Packets of Tylosin Soluble Powder | Volume of water to make Stock Solution |
|--|---|---|
| 250 mg/gallon (66ppm) | 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:

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 Tylosin Soluble Powder 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 Tylosin Soluble Powder. **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 Tylosin Soluble Powder.

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

Distributed by: MWI
Boise, ID 83705
www.VetOne.net

NDC 13985-710-05

Tylosin Soluble Powder

(tylosin tartrate)

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.

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

V1 510601

Equivalent to 100 g (3.53 oz) tylosin base

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Drug facts continued on inside panels. Pull open at top right.

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| TYLOSIN SOLUBLE POWDER | | | | |
|---|--|---------------------|----------------------|--------------------|
| tylosin tartrate powder, for solution | | | | |
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| Product Information | | | | |
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:13985-710 | |
| 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:13985-710-10 | 100 g in 1 PACKET | | |
| 2 | NDC:13985-710-05 | 100 g in 1 JAR | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| ANADA | ANADA200455 | | 08/27/2015 | |

Labeler - MWI/VetOne (019926120)