

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

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

Approved by FDA under ANADA # 200-473

Product 2220

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.

Restricted Drug (California) - Use Only as Directed.

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>.

Manufactured for: Huvepharma Inc.

Peachtree City, GA 30269, Made in Bulgaria

Tylovet® is a registered trademark of Huvepharma EOOD

Rev. 06-2022

Lot: 000000000000

Exp. Date: 00.0000

Code: LB444v5-Tyl100-

USA0622

Mixing Directions for Water Medicating Pump (1:128 inclusion)*:

| 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.

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 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.

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.

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: Store at 20-25 °C (68-77 °F). Excursions permitted to 40°C (104°F). Avoid Moisture.



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Tylosin Tartrate

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Macrolide Antibiotic
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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 disease (CRD) associated with *Mycoplasma gallisepticum* in broiler and layer chickens. For the control of CRD associated with *Mycoplasma gallisepticum* at the other stress in chickens. For the control of CRD associated with *Mycoplasma* in 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* spp. For the treatment and control of SD associated with *Brachyspira* spp. For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Brachyspira* spp. For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Brachyspira* spp.

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

Ingredients

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Dosages:

Dosage and Administration

Chickens:

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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 w
Tylovet Soluble solution every three days. When mixing and handling tylc
clothing and impervious gloves. If using a water medicating pump see tal
mix as follows:

To assure thorough dissolution, first place the contents of one pouch in a
add one gallon of water (3785 mL) to the powder to make a concentrated
medicated drinking water containing 250 mg/gallon (66 ppm), mix this o
with water to make 400 gallons (1514 liters) of medicated drinking water
drinking water containing 851 to 1,419 mg/gallon (225 to 375 ppm), mix th
solution with water to make from 117 gallons + 51 ounces (444 liters) to 7
(267 liters) of medicated drinking water, respectively. To make medicated
containing 2,000 mg/gallon (528 ppm), mix this concentrated solution wi
gallons (189 liters) of medicated drinking water.

Restricted Drug (California) - Use Only as Directed.

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assistance or to obtain a copy of the Safety Data Sheet
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Peachtree City, GA 30269, Made in Bulgaria

Tylovet® is a registered trademark of Huvepharma EOOD

Lot: 000000000000

Exp. Date: 00.0000

Rev. 06-

Code: L6

Mixing Directions for Water Medicating Pump (1:128 inclusion)^a:

| Desired Concentration in Drinking water | Pouches of Tylovet Soluble | Volume 5' |
|--|-------------------------------|--------------|
| 250 mg/gallon (66 ppm) | 1 | 3 galle |
| 851 mg/gallon (225 ppm) | 5 | 4 galle |
| 1,419 mg/gallon (375 ppm) | 9 | 5 galle |
| 2,000 mg/gallon (528 ppm) | 10 | 3 galle |

^aThis table applies only if the water medicating pump is set to deliver 1
per gallon of drinking water.

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

Directions for Use

Chickens: NE indication: Administer medicated drinking water for a sing
broiler chickens. To assure all birds receive the intended medication, onl
should be available. These practices should be followed to assure both f
responsible antimicrobial drug use in chickens. 1) Use in flocks exhibitin

Swine: SD indication: Administer medicated drinking water for 3 to 10 c severity of infection. Alternatively, administer medicated drinking water followed by 40 to 100 g tylosin per ton of complete feed (Type C medica from Tylovet Type A medicated article) for 2 to 6 weeks. Only medicated available to swine while medicating with Tylovet Soluble. **PPE indication** drinking water for 3 to 10 days, followed by 40 to 100 g of tylosin per ton (Type C medicated feed manufactured from Tylovet A medicated article). medicated water should be available to swine while medicating with Tyl **Honey Bee Colonies:** Administer three treatments of medicated confect weekly for 3 weeks. The 200 mg dose is applied (dusted) over the top ba chamber.

User Safety Warnings: Not for Human Use. Keep Out of Reach of Children. Do not apply to human skin. Exposure to tylosin may cause a rash.

Honey bees: The drug should be fed early in the spring or fall and the bees before the main honey flow begins, to avoid contaminating honey. Complete treatments at least 4 weeks prior to main honey.

Storage: Store at 20–25 °C (68–77 °F). Excursions permitted to 40 °C (104 °F).

tylosin tartrate powder, for solution

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|-------------------------|--------------------------|--------------------|----------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:23243-2220 |
| Route of Administration | ORAL | | |

| 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)

Revised: 1/2023

Huvepharma, Inc.