

**BILOVET- tylosin injection, solution**  
**Bimeda, Inc.**

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**BiloVet®**

**(tylosin injection)**

**For Use In Cattle and Swine Only**

**Use automatic syringe equipment only**

**200 mg per mL**

**An Antibiotic**

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**(tylosin injection)**

**For Use in Cattle and Swine Only**

**Use automatic syringe equipment only**

**200 mg per mL**

**An Antibiotic**

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

**INDICATIONS:** In Beef Cattle and Non-lactating Dairy Cattle, BiloVet is indicated for use in the treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes*.

In Swine, BiloVet is indicated for use in the treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

Each mL contains 200 mg of tylosin activity (as tylosin base) in 50% propylene glycol with 4% benzyl alcohol, water for injection and hydrochloric acid for pH adjustment.

**ADMINISTRATION AND DOSAGE:** BiloVet is administered intramuscularly.

Use automatic syringe equipment only

**BEEF CATTLE AND NON-LACTATING DAIRY CATTLE:** Inject intramuscularly 8 mg per pound of body weight one time daily (1 mL per 25 pounds). Treatment should be continued 24 hours following remission of disease signs, not to exceed 5 days. Do not inject more than 10 mL per site.

**SWINE:** Inject intramuscularly 4 mg per pound of body weight (1 mL per 50 pounds) twice daily. Treatment should be continued 24 hours following remission of disease signs, not to exceed 3 days. Do not inject more than 5 mL per site.

Read accompanying directions fully before use.

**CAUTION:** Do not mix BiloVet with other injectable solutions as this may cause a precipitation of the active ingredients.

**WARNINGS:**

NOT FOR HUMAN USE.

KEEP OUT OF REACH OF CHILDREN.

**Adverse reactions, including shock and death may result from overdose in baby pigs.**

Do not attempt injection into pigs weighing less than 25 pounds (0.5 mL) with the common syringe. It is recommended that tylosin 50 mg/mL injection be used in pigs weighing less than 25 lbs.

Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.

**RESIDUE WARNING:**

**Swine:**

Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug.

**RESIDUE WARNING:**

**Cattle:**

Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves.

If tylosin medicated drinking water is used as a follow-up treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

**STORE AT 20°C-25°C (68°F -77°F).** Use within 28 days of first puncture and puncture a maximum of 5 times with automatic syringe equipment. When using a draw-off spike or needle larger than 4-gauge, discard any product remaining in the vial immediately after use.

Approved by FDA under ANADA # 200-508

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 [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

**INDICATIONS:**  
**In Beef Cattle and Non-lactating Dairy Cattle:** Treatment of bovine respiratory complex (shipping fever, pneumonia), foot rot (peptic pododermatitis), calf diphtheria, and metritis.  
**In Swine:** Treatment of mycoplasma swine arthritis, swine pneumonia, swine erysipelas, and swine dysentery when followed by appropriate medication in the drinking water and/or feed.  
Each mL contains 200 mg of tylosin activity (as tylosin base) in 50% propylene glycol with 4% benzyl alcohol, water for injection and hydrochloric acid for pH adjustment.  
**ADMINISTRATION AND DOSAGE:** BiloVet is administered intramuscularly. Use automatic syringe equipment only.  
**Beef Cattle and Non-lactating Dairy Cattle:** Inject intramuscularly 8 mg per pound of body weight one time daily (1 mL per 25 pounds). Treatment should be continued 24 hours following remission of disease signs, not to exceed 5 days. Do not inject more than 10 mL per site.  
**Swine:** Inject intramuscularly 4 mg per pound of body weight (1 mL per 50 pounds) twice daily. Treatment should be continued 24 hours following remission of disease signs, not to exceed 3 days. Do not inject more than 5 mL per site.  
**Read accompanying directions fully before use.**  
**CAUTION:** Do not mix BiloVet with other injectable solutions as this may cause a precipitation of the active ingredients.

**500 mL**

**Residue Warning:** Swine: Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product.  
**Residue Warning:** Cattle: Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves.  
If tylosin medicated drinking water is used as a follow-up treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.  
**STORE AT 20°C - 25°C (68°F - 77°F).** Use within 28 days of first puncture and puncture a maximum of 5 times with automatic syringe equipment. When using a draw-off spike or needle larger than 4-gauge, discard any product remaining in the vial immediately after use.  
**Adverse reactions, including shock and death may result from overdosage in baby pigs.** Do not attempt injection into pigs weighing less than 25 pounds (0.5 mL) with the common syringe. It is recommended that tylosin 50 mg/mL injection be used in pigs weighing less than 25 pounds. Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.  
To report adverse effects, access medical information, or obtain additional product information, call 1-888-524-6332.

## BILOVET

tylosin injection, solution

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:61133-4011
<b>Route of Administration</b>	INTRAMUSCULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TYLOSIN</b> (UNII: YEF4JXN031) (TYLOSIN - UNII:YEF4JXN031)	TYLOSIN	200 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>water</b> (UNII: 059QF0K00R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-4011-2	250 mL in 1 BOTTLE, GLASS		
2	NDC:61133-4011-3	500 mL in 1 BOTTLE, GLASS		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200508	06/30/2021	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Bimeda- MTC		256232216	manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Biovet		645015512	api manufacture

**Establishment**

Name	Address	ID/FEI	Business Operations
Shandong Lukang Shelile Pharmaceutical Co. Ltd.		554404761	api manufacture