Special Offer

Take advantage of this special offer during the show!

Southern Livestock Supply Show | January 6-7, 2025

$35 rebate on every $1,000 purchase of select in-stock Elanco products.

Cattle Vaccines

- Bovine Pili Shield®
- Fusogard®
- Lepto Shield®
- Master Guard®
- NUPLURA® PH
- Pinkeye Shield® XT4
- ReproSTAR® L5 HB and VL5 HB
- Scour Bos®
- Somnu Shield®
- All Titanium® SKUs
- Vib Shield® Plus L5
- All Vira Shield® SKUs

Implants

- All Component® SKUs
- All Component® with Tylan® (trenbolone acetate and estradiol and tylosin tartrate implants) SKUs
- Component® with Tylan® E-C (progesterone and estradiol benzoate and tylosin tartrate implants)
- Compudose®
- Encore®

Anti-Infectives

- Micotil® (tilmicosin injection)
- Tylan® Injection (tylosin)
- Baytril® 100 (enrofloxacin) injection
- Increxxa™ (tulathromycin injection)
- Zelnate® DNA Immunostimulant

Insecticides

- Agita® 10 WG
- Beetle Shield® 6
- Catron® IV
- Clean-Up™ II Pour-On Insecticide with IGR
- Conquest™ Insecticide
- All Co-Ral® SKUs
- CyLence® Ultra Pest Control Concentrate
- CyLence® Ultra Premise Spray
- CyLence® Pour-On Insecticide
- Elector® PSP
- Neporex® 2 SG
- All Permectrin® SKUs
- All QuickBayt® SKUs
- Rabon® 50 WP Insecticide

Ear Tags

- Corathon®
- Cylence® Ultra Insecticide Cattle Ear Tag
- Patriot™ Cattle Insecticide Cattle Ear Tag

Cydectin® (moxidectin)

- Injectable
- Oral Drench
- Pour-On

Rebate will be offered in the form of a check from Elanco.

Rebate check provided upon validated purchase.

Offer exclusive to only listed products. See an Elanco representative for questions regarding product eligibility. Offer is exclusive to on-site purchases made during the Southern Livestock Supply Show, Jan. 6-7, 2025 and validated by the distributor prior to rebate being issued.

The labels contain complete use information, including cautions and warnings. Always read, understand and follow the labels and use directions.
Micotil (tilmicosin injection) is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni, and for the control of respiratory disease in cattle at high risk of developing BRD associated with Mannheimia haemolytica.

MICOTIL IMPORTANT SAFETY INFORMATION
Before using this product, it is important to read the entire product insert, including the boxed human warning. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Not for human use. Injection of this drug in humans has been associated with fatalities. Keep out of reach of children. Administer only with a tube-fed safety syringe. Do not use in automatically powered syringes or other delivery devices. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to injection site while avoiding direct contact with the skin. Avoid contact with eyes. Always use proper drug handling procedures to avoid accidental self-injection. Consult your veterinarian on the safe handling and use of all injectable products prior to administration. For use in cattle or sheep only. Inject subcutaneously. Injection of this antibiotic has been shown to be fatal in swine and non-human primates, and may be fatal in horses and goats. Do not use in female dairy cattle 20 months of age or older. Use in lactating dairy cattle or sheep may cause milk residues. The following adverse reactions have been reported: in cattle: injection site swelling and inflammation, lameness, collapse, anaphylaxis/anaphylactoid reactions, decreased food and water consumption and death. Micotil has a pre-slaughter withdrawal time of 42 days.

Zelnate is based on technology developed by Juvaris BioTherapeutics and is patent protected. Animal health applications are being developed exclusively under the rights of Elanco and are protected by patents.

Keep Cydectin out of reach of children.

Baytril and QuickBayt are sold by Elanco or its affiliates and are not Bayer products. The Baytril is a trademark owned by Bayer and used under license.

Elanco Baytril® 100

(enrofloxacin)

100 mg/mL Antimicrobial Injectable Solution

For Subcutaneous Use In Beef Cattle And Non-Lactating Dairy Cattle
For Intramuscular Or Subcutaneous Use In Swine
Not For Use In Female Dairy Cattle 20 Months Of Age Or Older
Or In Calves To Be Processed For Veal

CAUTION:

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.
Federal (U.S.A.) law prohibits the extra-label use of this drug in food-producing animals.

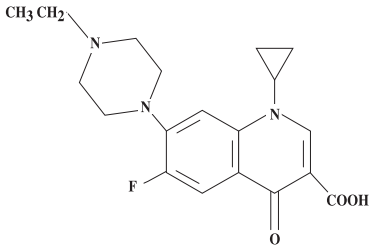
To assure responsible antimicrobial drug use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options.

PRODUCT DESCRIPTION:

Baytril 100 is a sterile, ready-to-use injectable antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent.
Each mL of Baytril 100 contains 100 mg of enrofloxacin. Excipients are L-arginine base 200 mg, n-butyl alcohol 30 mg, benzyl alcohol (as a preservative) 20 mg and water for injection q.s.

CHEMICAL NOMENCLATURE AND STRUCTURE:

1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.



INDICATIONS:

Cattle - Single-Dose Therapy: Baytril 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica, P. multocida, H. somni* and *M. bovis*.

Cattle - Multiple-Day Therapy: Baytril 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle.

Swine: Baytril 100 is indicated for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae.* Baytril 100 is indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

DOSAGE AND ADMINISTRATION:

Baytril 100 provides flexible dosages and durations of therapy.
Baytril 100 may be administered as a single dose for one day for treatment and control of BRD (cattle), for treatment and control of SRD or for control of colibacillosis (swine), or for multiple days for BRD treatment (cattle). Selection of the appropriate dose and duration of therapy for BRD treatment in cattle should be based on an assessment of the severity of the disease, pathogen susceptibility and clinical response.

Cattle:

Single-Dose Therapy (BRD Treatment): Administer, by subcutaneous injection, a single dose of 7.5-12.5 mg/kg of body weight (3.4-5.7 mL/100 lb).

Multiple-Day Therapy (BRD Treatment): Administer daily, a subcutaneous dose of 2.5-5 mg/kg of body weight (1.1-2.3 mL/100 lb). Treatment should be repeated at 24-hour intervals for three days. Additional treatments may be given on Days 4 and 5 to animals that have shown clinical improvement but not total recovery.

Single-Dose Therapy (BRD Control): Administer, by subcutaneous injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb).

Examples of conditions that may contribute to calves being at high risk of developing BRD include, but are not limited to, the following:

- Transportation with animals from two or more farm origins.
- An extended transport time with few to no rest stops.
- An environmental temperature change of ≥30°F during transportation.
- A ≥30°F range in temperature fluctuation within a 24-hour period.
- Exposure to wet or cold weather conditions.
- Excessive shrink (more than would be expected with a normal load of cattle).
- Stressful arrival processing procedures (e.g., castration or dehorning).
- Exposure within the prior 72 hours to animals showing clinical signs of BRD.

Administered dose volume should not exceed 20 mL per injection site.

Table 1 – Baytril 100 Dose and Treatment Schedule for Cattle*

Weight (lb)	Treatment		Control
	Single-Dose Therapy 7.5 - 12.5 mg/kg Dose Volume (mL)	Multiple-Day Therapy 2.5 - 5.0 mg/kg Dose Volume (mL)	Single-Dose Therapy 7.5 mg/kg Dose Volume (mL)
100	3.5 - 5.5	1.5 - 2.0	3.5
200	7.0 - 11.0	2.5 - 4.5	7.0
300	10.5 - 17.0	3.5 - 6.5	10.5
400	14.0 - 22.5	4.5 - 9.0	14.0
500	17.0 - 28.5	5.5 - 11.5	17.0
600	20.5 - 34.0	7.0 - 13.5	20.5
700	24.0 - 39.5	8.0 - 16.0	24.0
800	27.5 - 45.5	9.0 - 18.0	27.5
900	31.0 - 51.0	10.0 - 20.5	31.0
1000	34.0 - 57.0	11.0 - 23.0	34.0
1100	37.5 - 62.5	12.5 - 25.0	37.5

*Dose volumes have been rounded to the nearest 0.5 mL within the dose range.

Swine:

Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb). Administered dose volume should not exceed 5 mL per injection site.

For the control of colibacillosis, administration should be initiated within the first 60 days post-weaning when clinical signs are present in at least 2% of the animals in the group. If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

Table 2 – Baytril 100 Dose Schedule for Swine

Weight (lb)	Dose Volume (mL)
15	0.5
30	1.0
50	1.7
100	3.4
150	5.1
200	6.8
250	8.5

Dilution of Baytril 100: Baytril 100 may be diluted with sterile water prior to injection. The diluted product should be used within 24 hours. Store diluted solution in amber glass bottles between 4-40°C (36-104°F).

Table 3 – Dilution Schedule*

Swine Weight	mL of Baytril 100	mL of sterile water	Number of doses
10 lb	34 mL	66 mL	100
15 lb	51 mL	49 mL	100
20 lb	68 mL	32 mL	100
25 lb	85 mL	15 mL	100

*For 1 mL dose volume from diluted solution

Use within 30 days of first puncture and puncture a maximum of 30 times with a needle or 4 times with a dosage delivery device. Any product remaining beyond these parameters should be discarded.

RESIDUE WARNINGS:

Cattle: Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for 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. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. **Swine:** Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

HUMAN WARNINGS:

Not for use in humans. Keep out of reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposures. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.

PRECAUTIONS:

The effects of enrofloxacin on cattle or swine reproductive performance, pregnancy and lactation have not been adequately determined. The long-term effects on articular joint cartilage have not been determined in pigs above market weight.

Subcutaneous injection in cattle and swine, or intramuscular injection in swine, can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

Baytril 100 contains different excipients than other Baytril products. The safety and efficacy of this formulation in species other than cattle and swine have not been determined.

Quinolone-class drugs should be used with caution in animals with known or suspected Central Nervous System (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation which may lead to convulsive seizures. Quinolone-class drugs have been shown to produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species. See Animal Safety section for additional information.

ADVERSE REACTIONS:
No adverse reactions were observed during clinical trials.
For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

MICROBIOLOGY:
Enrofloxacin is bactericidal and exerts its antibacterial effect by inhibiting bacterial DNA gyrase (a type II topoisomerase) thereby preventing DNA supercoiling and replication which leads to cell death.[1] Enrofloxacin is active against Gram-negative and Gram-positive bacteria.

EFFECTIVENESS:
Cattle: A total of 845 calves with naturally-occurring BRD were treated with Baytril 100 in eight field trials located in five cattle-feeding states. Response to treatment was compared to non-treated controls. Single-dose and multiple-day therapy regimens were evaluated. BRD and mortality were significantly reduced in enrofloxacin-treated calves. No adverse reactions were reported in treated animals.
The effectiveness of Baytril 100 for the control of respiratory disease in cattle at high risk of developing BRD was evaluated in a six-location study in the U.S. and Canada. A total of 1,150 crossbred beef calves at high risk of developing BRD were enrolled in the study. Baytril 100 (7.5 mg/kg BW) or an equivalent volume of sterile saline was administered as a single subcutaneous injection within two days after arrival. Cattle were observed daily for clinical signs of BRD and were evaluated for success on Day 14 post-treatment. Treatment success in the Baytril 100 group (497/573, 87.83%) was significantly higher ($P = 0.0013$) than success in the saline control group (455/571, 80.92%). In addition, there were more treatment successes ($n = 13$) than failures ($n = 3$) in the group of animals positive for *M. bovis* on Day 0 that were treated with Baytril 100. No product-related adverse reactions were reported.
Swine: A total of 590 pigs were treated with Baytril 100 or saline in two separate natural infection SRD field trials. For the treatment of SRD, the success rate of enrofloxacin-treated pigs that were defined as "sick and febrile" (increased respiratory rate, labored or dyspneic breathing, depressed attitude and a rectal temperature ≥ 104°F) was statistically significantly greater than the success rate of saline-treated "sick and febrile" pigs. For the control of SRD, mean rectal temperature, mortality (one trial) and morbidity were statistically significantly lower for enrofloxacin-treated pigs in pens containing a percentage of "sick and febrile" pigs compared to saline-treated pigs.
The effectiveness of Baytril 100 administered as a single SC dose of 7.5 mg/kg BW for the treatment and control of SRD associated with *M. hyopneumoniae* was demonstrated using an induced infection model study and three single-site natural infection field studies. In the model study, 72 healthy pigs were challenged with a representative *M. hyopneumoniae* isolate and treated with Baytril 100 or saline. A statistically significant ($P < 0.0001$) decrease in the mean total lung lesion score was observed in the Baytril 100-treated group (4%) compared with the saline-treated group (27%) at 10 days post-treatment. In two field studies evaluating effectiveness for treatment of SRD, a total of 300 pigs with clinical signs of SRD (moderate depression, moderately increased respiratory rate, and a rectal temperature of ≥ 104°F) were enrolled and treated with Baytril 100 or saline. At 7 days post-treatment, the cure rate was statistically significantly higher at each site ($P < 0.0001$) in the Baytril 100-treated groups (61.3% and 92%) compared with the saline-treated groups (26.7% and 33.3%). In one field study evaluating effectiveness for control of SRD, a group of 400 pigs in which > 15% had clinical signs of SRD (moderate depression score, moderately increased respiratory rate, and a rectal temperature of ≥ 104°F) was enrolled and treated with Baytril 100 or saline. At 7 days post-treatment, the cure rate was statistically significantly higher ($P < 0.0002$) in the Baytril 100-treated group (70.0%) compared with the saline-treated group (48.5%). In addition to *M. hyopneumoniae, B. bronchiseptica* was also isolated in sufficient numbers from these field studies to be included in the SRD treatment and control indications.
The effectiveness of Baytril 100 for the control of colibacillosis associated with *E. coli* was evaluated in a multi-site natural infection field study. At each site, when at least 5% of the pigs were defined as "clinically affected" (presence of diarrhea and either depression or gauntness), all pigs were administered Baytril 100 as a single IM dose of 7.5 mg/kg BW or an equivalent dose volume of saline. At 7 days post-treatment, the success rate was statistically significantly higher ($P = 0.0350$) in the Baytril 100-treated group (61.5%) compared with the saline-treated group (44.7%).
The effectiveness of Baytril 100 administered as a single IM dose of 7.5 mg/kg BW for the treatment and control of SRD or as a single SC dose of 7.5 mg/kg BW for the control of colibacillosis was confirmed by demonstrating comparable serum enrofloxacin concentrations following IM or SC injection into the neck of healthy male and female pigs.

TOXICOLOGY:
The oral LD50 for laboratory rats was greater than 5000 mg/kg of body weight. Ninety-day feeding studies in dogs and rats revealed no observable adverse effects at treatment rates of 3 and 40 mg/kg respectively. Chronic studies in rats and mice revealed no observable adverse effects at 5.3 and 323 mg/kg respectively. There was no evidence of carcinogenic effect in laboratory animal models. A two-generation rat reproduction study revealed no effect with 10 mg/kg treatments. No teratogenic effects were observed in rabbits at doses of 25 mg/kg or in rats at 50 mg/kg.

ANIMAL SAFETY:
Cattle: Safety studies were conducted in feeder calves using single doses of 5, 15 and 25 mg/kg for 15 consecutive days and 50 mg/kg for 5 consecutive days. No clinical signs of toxicity were observed when a dose of 5 mg/kg was administered for 15 days. Clinical signs of depression, incoordination and muscle fasciculation were observed in calves when doses of 15 or 25 mg/kg were administered for 10 to 15 days. Clinical signs of depression, inappetance and incoordination were observed when a dose of 50 mg/kg was administered for 3 days. No drug-related abnormalities in clinical pathology parameters were identified. No articular cartilage lesions were observed after examination of stifle joints from animals administered 25 mg/kg for 15 days.
A safety study was conducted in 23-day-old calves using doses of 5, 15 and 25 mg/kg for 15 consecutive days. No clinical signs of toxicity or changes in clinical pathology parameters were observed. No articular cartilage lesions were observed in the stifle joints at any dose level at 2 days and 9 days following 15 days of drug administration.
An injection site study conducted in feeder calves demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue and underlying muscle. No painful responses to administration were observed.
Swine: Subcutaneous Safety: A safety study was conducted in 32 pigs weighing approximately 57 kg (125 lb) using single doses of 5, 15 or 25 mg/kg daily for 15 consecutive days. Incidental lameness of short duration was observed in all groups, including the saline-treated controls. Musculoskeletal stiffness was observed following the 15 and 25 mg/kg treatments with clinical signs appearing during the second week of treatment. Clinical signs of lameness improved after treatment ceased and most animals were clinically normal at necropsy.
A second study was conducted in two pigs weighing approximately 23 kg (50 lb), treated with 50 mg/kg for 5 consecutive days. There were no clinical signs of toxicity or pathological changes
An injection site study conducted in pigs demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue. No painful responses to administration were observed.
Intramuscular Safety: A safety study was conducted in 48 weaned, 20- to 22-day-old pigs. Pigs were administered Baytril 100, at 7.5, 22.5 and 37.5 mg/kg BW by IM injection into the neck once weekly for 3 consecutive weeks. All pigs remained clinically normal throughout the study. Transient decreases in feed and water consumption were observed after each treatment. Mild, transient, post-treatment injection site swellings were observed in pigs receiving the 37.5 mg/kg BW dose. Injection site inflammation was found on post-mortem examination in all enrofloxacin-treated groups.

STORAGE CONDITIONS: Protect from direct sunlight. Do not refrigerate or freeze. Store at 20-30ºC (68-86ºF), excursions permitted up to 40ºC (104ºF). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

HOW SUPPLIED:
Baytril 100:

100 mg/mL	100 mL Bottle
100 mg/mL	250 mL Bottle
100 mg/mL	500 mL Bottle

REFERENCES:
1. Hooper, D. C., Wolfson, J. S., Quinolone Antimicrobial Agents, 2nd ed, 59 - 75, 1993.
For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.

Revised: January 2022

Baytril 100
Approved by FDA under NADA # 141-068
Manufactured for: Elanco US Inc.
Greenfield, IN 46140 U.S.A
Made in Germany

Elanco™

Elanco™ Increxxa™ (tulathromycin injection)

Injectable Solution

Antibiotic

100 mg of tulathromycin/mL

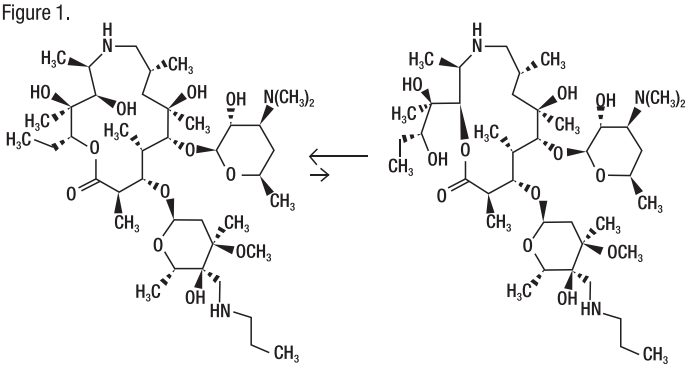
For use in beef cattle (including suckling calves), non-lactating dairy cattle (including dairy calves), veal calves, and swine. Not for use in female dairy cattle 20 months of age or older.

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

DESCRIPTION

Increxxa Injectable Solution is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamilide. Each mL of Increxxa contains 100 mg of tulathromycin, 500 mg propylene glycol, 19.2 mg citric acid and 5 mg monothioglycerol. Sodium hydroxide or hydrochloric acid may be added to adjust pH. Increxxa consists of an equilibrated mixture of two isomeric forms of tulathromycin in a 9:1 ratio. Structures of the isomers are shown below.

Figure 1.



The chemical names of the isomers are (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C-[(propylamino) methyl]-α-L-ribo-hexopyrano-syl]oxy]-2-ethyl-3,4,10- trihydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]-oxy]-1-oxa-6-azacyclopentadecan-15-one and (2R,3R,6R,8R,9R,10S,11S,12R)-11-[[2,6-dideoxy-3-C-methyl- 3-O-methyl-4-C-[(propylamino)methyl]-α-L-ribo-hexopyrano-syl]oxy]-2-[(1R,2R)-1,2-dihydroxy-1-methylbutyl]-8-hydroxy-3,6,8,10,12-pentamethyl-9-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-4-azacyclotridecan-13-one, respectively.

INDICATIONS

Beef and Non-Lactating Dairy Cattle

BRD – Increxxa Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

IBK – Increxxa Injectable Solution is indicated for the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

Foot Rot – Increxxa Injectable Solution is indicated for the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

Suckling Calves, Dairy Calves, and Veal Calves

BRD – Increxxa Injectable Solution is indicated for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*.

Swine

Increxxa Injectable Solution is indicated for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* in groups of pigs where SRD has been diagnosed.

DOSAGE AND ADMINISTRATION

Cattle

Inject subcutaneously as a single dose in the neck at a dosage of 2.5 mg/kg (1.1 mL/100 lb) body weight (BW). Do not inject more than 10 mL per injection site.

Table 1. Increxxa Cattle Dosing Guide

Animal Weight (Pounds)	Dose Volume (mL)
100	1.1
200	2.3
300	3.4
400	4.5
500	5.7
600	6.8
700	8.0
800	9.1
900	10.2
1000	11.4

Swine

Inject intramuscularly as a single dose in the neck at a dosage of 2.5 mg/kg (0.25 mL/22 lb) BW. Do not inject more than 2.5 mL per injection site.

Table 2. Increxxa Swine Dosing Guide

Animal Weight (Pounds)	Dose Volume (mL)
15	0.2
30	0.3
50	0.6
70	0.8
90	1.0
110	1.3
130	1.5
150	1.7
170	1.9
190	2.2
210	2.4
230	2.6
250	2.8
270	3.1
290	3.3

CONTRAINDICATIONS

The use of Increxxa Injectable Solution is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS

FOR USE IN ANIMALS ONLY.

NOT FOR HUMAN USE.

KEEP OUT OF REACH OF CHILDREN.

NOT FOR USE IN CHICKENS OR TURKEYS.

RESIDUE WARNINGS

Cattle

Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug 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.

Swine

Swine intended for human consumption must not be slaughtered within 5 days from the last treatment.

PRECAUTIONS

Cattle

The effects of Increxxa on bovine reproductive performance, pregnancy, and lactation have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

Swine

The effects of Increxxa on porcine reproductive performance, pregnancy, and lactation have not been determined. Intramuscular injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS

Cattle

In one BRD field study, two calves treated with tulathromycin injection at 2.5 mg/kg BW exhibited transient hypersalivation. One of these calves also exhibited transient dyspnea, which may have been related to pneumonia.

Swine

In one field study, one out of 40 pigs treated with tulathromycin injection at 2.5 mg/kg BW exhibited mild salivation that resolved in less than four hours.

POST APPROVAL EXPERIENCE

The following adverse events are based on post approval adverse drug experience reporting. Not all adverse events are reported to the FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are listed in decreasing order of reporting frequency in cattle: Injection site reactions and anaphylaxis/anaphylactoid reactions. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY

At physiological pH, tulathromycin (a weak base) is approximately 50 times more soluble in hydrophilic than hydrophobic media. This solubility profile is consistent with the extracellular pathogen activity typically associated with the macrolides.[1] Markedly higher tulathromycin concentrations are observed in the lungs as compared to the plasma. The extent to which lung concentrations represent free (active) drug was not examined. Therefore, the clinical relevance of these elevated lung concentrations is undetermined. Although the relationship between tulathromycin and the characteristics of its antimicrobial effects has not been characterized, as a class, macrolides tend to be primarily bacteriostatic, but may be bactericidal against some pathogens.[2] They also tend to exhibit concentration independent killing; the rate of bacterial eradication does not change once serum drug concentrations reach 2 to 3 times the minimum inhibitory concentration (MIC) of the targeted pathogen. Under these conditions, the time that serum concentrations remain above the MIC becomes the major determinant of antimicrobial activity. Macrolides also exhibit a post-antibiotic effect (PAE), the duration of which tends to be both drug and pathogen dependent. In general, by increasing the macrolide concentration and the exposure time, the PAE will increase to some maximal duration. Of the two variables, concentration and exposure time, drug concentration tends to be the most powerful determinant of the duration of PAE. Tulathromycin is eliminated from the body primarily unchanged via biliary excretion.

1 *Carbon, C. 1998. Pharmacodynamics of Macrolides, Azalides, and Streptogramins: Effect on Extracellular Pathogens. Clin. Infect. Dis., **27**:28-32.*

2 *Nightingale, C.J. 1997. Pharmacokinetics and Pharmacodynamics of Newer Macrolides. Pediatr. Infect. Dis. J., **16**:438-443.*

Cattle

Following subcutaneous administration into the neck of feeder calves at a dosage of 2.5 mg/kg BW, tulathromycin is rapidly and nearly completely absorbed. Peak plasma concentrations generally occur within 15 minutes after dosing and product relative bioavailability exceeds 90%. Total systemic clearance is approximately 170 mL/hr/kg. Tulathromycin distributes extensively into body tissues, as evidenced by volume of distribution values of approximately 11 L/kg in healthy ruminating calves.[3] This extensive volume of distribution is largely responsible for the long elimination half-life of this compound [approximately 2.75 days in the plasma (based on quantifiable terminal plasma drug concentrations) versus 8.75 days for total lung concentrations (based on data from healthy animals)]. Linear pharmacokinetics are observed with subcutaneous doses ranging from 1.27 mg/kg BW to 5.0 mg/kg BW. No pharmacokinetic differences are observed in castrated male versus female calves.

3 *Clearance and volume estimates are based on intersubject comparisons of 2.5 mg/kg BW administered by either subcutaneous or intravenous injection.*

Swine

Following intramuscular administration to feeder pigs at a dosage of 2.5 mg/kg BW, tulathromycin is completely and rapidly absorbed (T_{max} ~0.25 hour). Subsequently, the drug rapidly distributes into body tissues, achieving a volume of distribution exceeding 15 L/kg. The free drug is rapidly cleared from the systemic circulation ($CL_{systemic}$= 187 mL/hr/kg). However, it has a long terminal elimination half-life (60 to 90 hours) owing to its extensive volume of distribution. Although pulmonary tulathromycin concentrations are substantially higher than concentrations observed in the plasma, the clinical significance of these findings is undetermined. There are no gender differences in swine tulathromycin pharmacokinetics.

MICROBIOLOGY

Cattle

Tulathromycin has demonstrated *in vitro* activity against *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, four pathogens associated with BRD; against *Moraxella bovis* associated with IBK; and against *Fusobacterium necrophorum* and *Porphyromonas levii* associated with bovine foot rot. The MICs of tulathromycin against indicated BRD and IBK pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, M31-A2). The MICs against foot rot pathogens were also determined using methods recommended by the CLSI (M11-A6). All MIC values were determined using the 9:1 isomer ratio of this compound.

BRD - The MICs of tulathromycin were determined for BRD isolates obtained from calves enrolled in therapeutic and at-risk field studies in the U.S. in 1999. In the therapeutic studies, isolates were obtained from pre-treatment nasopharyngeal swabs from all study calves, and from lung swabs or lung tissue of saline-treated calves that died. In the at-risk studies, isolates were obtained from nasopharyngeal swabs of saline-treated non-responders, and from lung swabs or lung tissue of saline-treated calves that died. The results are shown in Table 3.

IBK - The MICs of tulathromycin were determined for *Moraxella bovis* isolates obtained from calves enrolled in IBK field studies in the U.S. in 2004. Isolates were obtained from pre-treatment conjunctival swabs of calves with clinical signs of IBK enrolled in the tulathromycin injection and saline-treated groups. The results are shown in Table 3.

Foot Rot - The MICs of tulathromycin were determined for *Fusobacterium necrophorum* and *Porphyromonas levii* obtained from cattle enrolled in foot rot field studies in the U.S. and Canada in 2007. Isolates were obtained from pre-treatment interdigital biopsies and swabs of cattle with clinical signs of foot rot enrolled in the tulathromycin injection and saline-treated groups. The results are shown in Table 3.

Table 3. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating BRD and IBK in the U.S. and from foot rot field studies in the U.S. and Canada.

Indicated pathogen	Date isolated	No. of isolates	MIC_{50} ** (µg/mL)	MIC_{90} ** (µg/mL)	MIC range (µg/mL)
Mannheimia haemolytica	1999	642	2	2	0.5 to 64
Pasteurella multocida	1999	221	0.5	1	0.25 to 64
Histophilus somni	1999	36	4	4	1 to 4
Mycoplasma bovis	1999	43	0.125	1	≤ 0.063 to > 64
Moraxella bovis	2004	55	0.5	0.5	0.25 to 1
Fusobacterium necrophorum	2007	116	2	64	≤ 0.25 to > 128
Porphyromonas levii	2007	103	8	128	≤ 0.25 to > 128

* The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

Swine

In vitro activity of tulathromycin has been demonstrated against *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*.

The MICs of tulathromycin against indicated SRD pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, M31-A and M31-A3). MICs for *Haemophilus parasuis* were determined using Veterinary Fastidious Medium and were incubated up to 48 hours at 35 to 37°C in a CO_2-enriched atmosphere. All MIC values were determined using the 9:1 isomer ratio of this compound. Isolates obtained in 2000 and 2002 were from lung samples from saline-treated pigs and non-treated sentinel pigs enrolled in Treatment of SRD field studies in the U.S. and Canada. Isolates obtained in 2007 and 2008 were from lung samples from saline-treated and tulathromycin injection-treated pigs enrolled in the Control of SRD field study in the U.S. and Canada. The results are shown in Table 4.

Table 4. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating SRD in the U.S. and Canada.

Indicated pathogen	Date isolated	No. of isolates	MIC_{50} ** (µg/mL)	MIC_{90} ** (µg/mL)	MIC range (µg/mL)
Actinobacillus pleuropneumoniae	2000-2002	135	16	32	16 to 32
	2007-2008	88	16	16	4 to 32
Haemophilus parasuis	2000-2002	31	1	2	0.25 to > 64
Pasteurella multocida	2000-2002	55	1	2	0.5 to > 64
	2007-2008	40	1	2	≤ 0.03 to 2
Bordetella bronchiseptica	2000-2002	42	4	8	2 to 8

* The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

EFFECTIVENESS

Cattle

BRD – In a multi-location field study, 314 calves with naturally occurring BRD were treated with tulathromycin injection. Responses to treatment were compared to saline-treated controls. A cure was defined as a calf with normal attitude/activity, normal respiration, and a rectal temperature of ≤ 104°F on Day 14. The cure rate was significantly higher ($P \leq 0.05$) in tulathromycin injection-treated calves (78%) compared to saline-treated calves (24%). There were two BRD-related deaths in the tulathromycin injection-treated calves compared to nine BRD-related deaths in the saline-treated calves. Fifty-two tulathromycin injection-treated calves and 27 saline-treated calves from the multi-location field BRD treatment study had *Mycoplasma bovis* identified in cultures from pre-treatment nasopharyngeal swabs. Of the 52 tulathromycin injection-treated calves, 37 (71.2%) calves were categorized as cures and 15 (28.8%) calves were categorized as treatment failures. Of the 27 saline-treated calves, 4 (14.8%) calves were categorized as cures and 23 (85.2%) calves were treatment failures.

A Bayesian meta-analysis was conducted to compare the BRD treatment success rate in young calves (calves weighing 250 lbs or less and fed primarily a milk-based diet) treated with tulathromycin injection to the success rate in older calves (calves weighing more than 250 lbs and fed primarily a roughage and grain-based diet) treated with tulathromycin injection. The analysis included data from four BRD treatment effectiveness studies conducted for the approval of tulathromycin injection in the U.S. and nine contemporaneous studies conducted in Europe. The analysis showed that the BRD treatment success rate in young calves was at least as good as the BRD treatment success rate in older calves. As a result, tulathromycin injection is considered effective for the treatment of BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis* in suckling calves, dairy calves, and veal calves.

In another multi-location field study with 399 calves at high risk of developing BRD, administration of tulathromycin injection resulted in a significantly reduced incidence of BRD (11%) compared to saline-treated calves (59%). Effectiveness evaluation was based on scored clinical signs of normal attitude/activity, normal respiration, and a rectal temperature of ≤ 104°F on Day 14. There were no BRD-related deaths in the tulathromycin injection-treated calves compared to two BRD-related deaths in the saline-treated calves.

Fifty saline-treated calves classified as non-responders in this study had *Mycoplasma bovis* identified in cultures of post-treatment nasopharyngeal swabs or lung tissue.

Two induced infection model studies were conducted to confirm the effectiveness of tulathromycin injection against *Mycoplasma bovis*. A total of 166 calves were inoculated intratracheally with field strains of *Mycoplasma bovis*. When calves became pyrexic and had abnormal respiration scores, they were treated with either tulathromycin injection (2.5 mg/kg BW) subcutaneously or an equivalent volume of saline. Calves were observed for signs of BRD for 14 days post-treatment, then were euthanized and necropsied. In both studies, mean lung lesion percentages were statistically significantly lower in the tulathromycin injection-treated calves compared with saline-treated calves (11.3% vs. 28.9%, P = 0.0001 and 15.0% vs. 30.7%, P < 0.0001).

IBK – Two field studies were conducted evaluating tulathromycin injection for the treatment of IBK associated with *Moraxella bovis* in 200 naturally-infected calves. The primary clinical endpoint of these studies was cure rate, defined as a calf with no clinical signs of IBK and no corneal ulcer, assessed on Days 5, 9, 13, 17, and 21. Time to improvement, defined as the first day on which a calf had no clinical signs of IBK in both eyes, provided that those scores were maintained at the next day of observation, was assessed as a secondary variable. At all time points, in both studies, the cure rate was significantly higher (P < 0.05) for tulathromycin injection-treated calves compared to saline-treated calves. Additionally, time to improvement was significantly less (P < 0.0001) in both studies for tulathromycin injection-treated calves compared to saline-treated calves.

Foot Rot - The effectiveness of tulathromycin injection for the treatment of bovine foot rot was evaluated in 170 cattle in two field studies. Cattle diagnosed with bovine foot rot were enrolled and treated with a single subcutaneous dose of tulathromycin injection (2.5 mg/kg BW) or an equivalent volume of saline. Cattle were clinically evaluated 7 days after treatment for treatment success, which was based on defined decreases in lesion, swelling, and lameness scores. In both studies, the treatment success percentage was statistically significantly higher in tulathromycin injection-treated calves compared with saline-treated calves (60% vs. 8%, P < 0.0001 and 83.3% vs. 50%, P = 0.0088).

Swine

In a multi-location field study to evaluate the treatment of naturally occurring SRD, 266 pigs were treated with tulathromycin injection. Responses to treatment were compared to saline-treated controls. Success was defined as a pig with normal attitude, normal respiration, and rectal temperature of < 104°F on Day 7. The treatment success rate was significantly greater (P ≤ 0.05) in tulathromycin injection-treated pigs (70.5%) compared to saline-treated pigs (46.1%). *M. hyopneumoniae* was isolated from 106 saline-treated and non-treated sentinel pigs in this study.

Two induced infection model studies were conducted to confirm the effectiveness of tulathromycin injection against *M. hyopneumoniae*. Ten days after inoculation intranasally and intratracheally with a field strain of *M. hyopneumoniae*, 144 pigs were treated with either tulathromycin injection (2.5 mg/kg BW) intramuscularly or an equivalent volume of saline. Pigs were euthanized and necropsied 10 days post-treatment. The mean percentage of gross pneumonic lung lesions was statistically significantly lower (P < 0.0001) for tulathromycin injection-treated pigs than for saline-treated pigs in both studies (8.52% vs. 23.62% and 11.31% vs. 26.42%).

The effectiveness of tulathromycin injection for the control of SRD was evaluated in a multi-location natural infection field study. When at least 15% of the study candidates showed clinical signs of SRD, all pigs were enrolled and treated with tulathromycin injection (226 pigs) or saline (227 pigs). Responses to treatment were evaluated on Day 7. Success was defined as a pig with normal attitude, normal respiration, and rectal temperature of < 104°F. The treatment success rate was significantly greater (P < 0.05) in tulathromycin injection-treated pigs compared to saline-treated pigs (59.2% vs. 41.2%).

ANIMAL SAFETY

Cattle

Safety studies were conducted in feeder calves receiving a single subcutaneous dose of 25 mg/kg BW, or 3 weekly subcutaneous doses of 2.5, 7.5, or 12.5 mg/kg BW. In all groups, transient indications of pain after injection were seen, including head shaking and pawing at the ground. Injection site swelling, discoloration of the subcutaneous tissues at the injection site and corresponding histopathologic changes were seen in animals in all dosage groups. These lesions showed signs of resolving over time. No other drug-related lesions were observed macroscopically or microscopically. An exploratory study was conducted in feeder calves receiving a single subcutaneous dose of 10, 12.5, or 15 mg/kg BW. Macroscopically, no lesions were observed. Microscopically, minimal to mild myocardial degeneration was seen in one of six calves administered 12.5 mg/kg BW and two of six calves administered 15 mg/kg BW.

A safety study was conducted in preruminant calves 13 to 27 days of age receiving 2.5 mg/kg BW or 7.5 mg/kg BW once subcutaneously. With the exception of minimal to mild injection site reactions, no drug-related clinical signs or other lesions were observed macroscopically or microscopically.

Swine

Safety studies were conducted in pigs receiving a single intramuscular dose of 25 mg/kg BW, or 3 weekly intramuscular doses of 2.5, 7.5, or 12.5 mg/kg BW. In all groups, transient indications of pain after injection were seen, including restlessness and excessive vocalization. Tremors occurred briefly in one animal receiving 7.5 mg/kg BW. Discoloration and edema of injection site tissues and corresponding histopathologic changes were seen in animals at all dosages and resolved over time. No other drug-related lesions were observed macroscopically or microscopically.

STORAGE CONDITIONS

Store below 25°C (77°F), with excursions up to 40°C (104°F).

100 mL: Use within 2 months of first puncture and puncture a maximum of 67 times. If more than 67 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16 gauge, discard any product remaining in the vial immediately after use.

250 mL: Use within 2 months of first puncture and puncture a maximum of 100 times. If more than 100 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16 gauge, discard any product remaining in the vial immediately after use.

HOW SUPPLIED

Increxxa (tulathromycin injection) Injectable Solution is available in the following package sizes:

100 mL vial
250 mL vial
500 mL vial

For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Approved by FDA under ANADA # 200-666

Product of China.

Manufactured for: Elanco US Inc., Greenfield, IN 46140 U.S.A.

Revised: May 2022

Elanco™

Micotil™ 300

250 mL™

(tilmicosin injection)

300 mg tilmicosin, USP as tilmicosin phosphate per mL

For Subcutaneous Use in Cattle and Sheep Only

Solo Para Uso Subcutáneo en Ganado Vacuno y Ovino

Approved by FDA under NADA # 140-929

Administer only with a tube-fed safety syringe. Do not use in automatically powered syringes, single-use syringes, or other delivery devices.
Contact Elanco at 1-800-428-4441, or your distributor, for a tube-fed safety syringe for use with this product.
Administrar únicamente con una jeringa de seguridad con tubo. No administrar con jeringas accionadas automáticamente, jeringas de un solo uso u otros dispositivos de aplicación. Contactar a Elanco al 1-800-428-4441, o al distribuidor, para obtener una jeringa de seguridad con tubo para usar con este producto.

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

Description: Micotil (tilmicosin injection) is a solution of the antibiotic tilmicosin. Each mL contains 300 mg of tilmicosin, USP as tilmicosin phosphate in 25% propylene glycol, phosphoric acid as needed to adjust pH and water for injection, Q.S. Tilmicosin, USP is produced semi-synthetically and is in the macrolide class of antibiotics.

Indications: Micotil is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* and for the treatment of ovine respiratory disease (ORD) associated with *Mannheimia haemolytica*. Micotil is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*.

Micotil must be used with the quick-fit connector made specifically for its use. Contact Elanco or your distributor for this equipment. Read product labeling, including Safe Handling Practices, before use.

Micotil debe usarse con un conector de ajuste rápido hecho específicamente para su uso. Contacte a Elanco o al distribuidor para obtener este equipo. Lea la ficha técnica, incluidas las Prácticas De Manejo Seguro, antes de usar.

Dosage and Administration: Follow instructions for activation of the shroud before first usage.

Inject Subcutaneously in Cattle and Sheep Only. See Safe Handling Practices, Contraindications, and Warnings prior to use. In cattle, administer a single subcutaneous dose of 10 to 20 mg/kg of body weight (1 to 2 mL/30 kg or 1.5 to 3 mL per 100 lbs). **In sheep** greater than 15 kg, administer a single subcutaneous dose of 10 mg/kg of body weight (1 mL/30 kg or 1.5 mL per 100 lbs). Do not inject more than 10 mL per injection site.
If no improvement is noted within 48-hours, the diagnosis should be reevaluated.
For cattle and sheep, injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulders and over the ribs.

Note: Swelling at the subcutaneous site of injection may be observed.

CONTRAINDICATIONS: Do not use in automatically powered syringes, single-use syringes, or other delivery devices not specified in the labeling. Do not administer intravenously to cattle or sheep.
Intravenous injection in cattle or sheep will be fatal. Do not use in lambs less than 15 kg body weight. Do not administer to animals other than cattle or sheep. Injection of tilmicosin has been shown to be fatal in swine and non-human primates. Death following exposure to tilmicosin injection has been reported to FDA/CVM in goats, rabbits, pheasants, pigs, dogs, deer, cats, alpacas, and horses.

Warnings:

HUMAN WARNINGS: Not for human use. Injection of this drug in humans has been associated with fatalities. Keep out of reach of children. Administer only with a tube-fed safety syringe. Do not use in automatically powered syringes, single-use syringes, or other delivery devices. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to injection site while avoiding direct contact with the skin. Emergency medical telephone numbers are 1-800-722-0987 or 1-800-428-4441. Avoid contact with skin, eyes, or mucous membranes.

NOTE TO THE PHYSICIAN: The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to calcium channel blockade. In dogs, administration of intravenous calcium offset Micotil-induced tachycardia and negative inotropy (decreased contractility). Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. ß-adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.

ADVERTENCIAS PARA EL SER HUMANO: Este producto no es para uso humano. La inyección de este medicamento al ser humano se ha asociado con muertes. Mantenga fuera del alcance de los niños. Utilice únicamente con una jeringa de seguridad con tubo. No use en jeringas operadas automáticamente, jeringas de un solo uso u otros dispositivos de aplicación. Proceda con extrema cautela para evitar la autoinyección accidental. En caso de inyección en seres humanos, consulte inmediatamente a un médico y aplique hielo o una compresa fría en el lugar de la inyección, evitando el contacto directo con la piel. Los números de teléfono para emergencias médicas son 1-800-722-0987 o 1-800-428-4441. Evite el contacto con la piel, los ojos o las membranas mucosas.

NOTA PARA EL MÉDICO: El sistema cardiovascular es el blanco de la toxicidad y debe vigilarse estrechamente. La toxicidad cardiovascular puede deberse al bloqueo de los canales de calcio.
En los perros, la administración intravenosa de calcio compensó la taquicardia y los efectos inotrópicos negativos (reducción de la contractilidad) inducidos por Micotil (tilmicosina inyectable). La dobutamina compensó parcialmente los efectos inotrópicos negativos inducidos por Micotil en perros. Los antagonistas ß-adrenérgicos, como propranolol, exacerbaron el inotropismo negativo de Micotil en los perros. La epinefrina potenció la letalidad de Micotil en cerdos. Este antibiótico persiste en los tejidos por varios días.

Residue Warnings: Animals intended for human consumption must not be slaughtered within 42 days of the last treatment. Not for use in lactating dairy cattle 20 months of age or older. Use of tilmicosin in this class of cattle may cause milk residues. Not for use in lactating ewes producing milk for human consumption.

Precautions: The effects of tilmicosin on bovine and ovine reproductive performance, pregnancy and lactation have not been determined. Intramuscular injection will cause a local reaction which may result in trim loss of edible tissue at slaughter.

Adverse Reactions: The following adverse reactions have been reported post-approval: In cattle: injection site swelling and inflammation, lameness, collapse, anaphylaxis/anaphylactoid reactions, decreased food and water consumption, and death.

In sheep: dyspnea and death.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

Clinical Pharmacology: A single subcutaneous injection of Micotil (tilmicosin injection) at 10 mg/kg of body weight dose in cattle resulted in peak tilmicosin levels within one hour and detectable levels (0.07 µg/mL) in serum beyond 3 days. However, lung concentrations of tilmicosin remained above the tilmicosin MIC 95% of 3.12 µg/mL for *Mannheimia haemolytica* for at least 3 days following the single injection. Serum tilmicosin levels are a poor indicator of total body tilmicosin. The lung/serum tilmicosin ratio in favor of lung tissue appeared to equilibrate by 3 days post-injection at approximately 60. In a study with radioactive tilmicosin, 24% and 68% of the dose was recovered from urine and feces respectively over 21 days. After a single subcutaneous injection of Micotil at 10 mg/kg of body weight, tilmicosin concentrations in excess of 4 µg/mL were maintained in the alveolar macrophages and neutrophils of most cattle for at least 10 days. The clinical relevance of these findings has not been determined.

Microbiology: Tilmicosin has an *in vitro* antibacterial spectrum that is predominantly Gram-positive with activity against certain Gram-negative microorganisms. *In vitro* activity against several *Mycoplasma* species has also been observed.

Effectiveness: In a multi-location field study, 1508 calves with naturally occurring BRD were treated with Micotil. Responses to treatment were compared to saline-treated controls. A cure was defined as a calf with normal attitude and activity, normal respiration, and a rectal temperature of <104°F on Day 13. The cure rate was significantly higher (P=0.004) in Micotil-treated calves (63.1%) compared to saline-treated calves (29.2%). During the treatment phase of the study, there were 10 BRD-related deaths in the Micotil-treated calves compared to 47 in the saline-treated calves.

Animal Safety: A safety study was conducted in feeder calves receiving subcutaneous doses of 20, 30, 40, or 60 mg/kg of body weight, injected 3 times at 72-hour intervals. Death was not seen in any of the treatment groups. Injection site swelling and mild hemorrhage at the injection site were seen in animals in all dosage groups. Lesions were described as being generally more severe and occurred at higher frequency rates in the animals treated with higher doses of tilmicosin. Lameness associated with the injection site was noted in two of twenty-four animals (one animal in the 30 mg/kg body weight treatment group and one animal in the 60 mg/kg treatment group). No other drug related lesions were observed macroscopically or microscopically. Decreases in food and water consumption were noted in all treatment groups compared to the control group.

A separate safety study conducted in feeder calves, subcutaneous doses of 10, 30, or 50 mg/kg of body weight, injected 3 times at 72-hour intervals did not cause any deaths. Edema at the site of injection was noted. The only lesion observed at necropsy was minimal myocardial necrosis in some animals dosed at 50 mg/kg.

In an additional safety study, subcutaneous doses of 150 mg/kg body weight injected at 72-hour intervals resulted in death of two of the four treated animals. Edema was marked at the site of injection. Minimal myocardial necrosis was the only lesion observed at necropsy. Deaths of cattle have been observed with a single intravenous dose of 5 mg/kg of body weight.

In sheep, single subcutaneous injections of 10 mg/kg body weight dose did not cause any deaths and no adverse effects of tilmicosin were observed on blood pressure, heart rate, or respiratory rate.

Toxicology: The heart is the target of toxicity in laboratory and domestic animals given Micotil (tilmicosin injection) by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy). Cardiovascular toxicity may be due to calcium channel blockade.

Upon subcutaneous injection, the acute median lethal dose of tilmicosin in mice is 97 mg/kg, and in rats is 185 mg/kg of body weight. Given orally, the median lethal dose is 800 mg/kg and 2250 mg/kg body weight in fasted and nonfasted rats, respectively.

No compound-related lesions were found at necropsy.

In dogs, intravenous calcium offset Micotil-induced tachycardia and negative inotropy, restoring arterial pulse pressure. Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. ß- adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs.

In monkeys, a single intramuscular dose of 10 mg/kg body weight caused no signs of toxicity. A single dose of 20 mg/kg body weight caused vomiting and 30 mg/kg body weight caused the death of the only monkey tested.

In swine, intramuscular injection of 10 mg/kg body weight caused increased respiration, emesis, and a convulsion, 20 mg/kg body weight resulted in mortality in 3 of 4 pigs, and 30 mg/kg body weight caused the death of all 4 pigs tested. Injection of 4.5 and 5.6 mg/kg body weight intravenously followed by epinephrine, 1mL (1:1000) intravenously 2 to 6 times, resulted in death of all pigs injected. Pigs given 4.5 mg/kg and 5.6 mg/kg body weight intravenously with no epinephrine all survived.

These results suggest intravenous epinephrine may be contraindicated.

Results of genetic toxicology studies were all negative. Results of teratology and reproduction studies in rats were negative.
The no effect level in dogs after daily oral doses for up to one year is 4 mg/kg of body weight.

Storage Conditions: Store at or below 86°F (30°C). Protect from direct sunlight. Use within 84 days of first puncture. Store upright between product dispensing. Disconnect and clean dosing equipment for storing as per manufacturer's instructions.
Conservar a 86 °F (30 °C). Proteger de la luz solar directa. Usar dentro de los 84 días de la primera punción. Guardar en posición vertical entre cada suministro del producto. Desconectar y limpiar el dispositivo de dosificación para el almacenamiento según las instrucciones del fabricante.

To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

How Supplied: Micotil (tilmicosin injection) is supplied in 250 mL multi-dose amber glass bottles in a non-removable polymer protector.

Manufactured for: **Elanco US, Inc. Greenfield, IN 46140, USA**

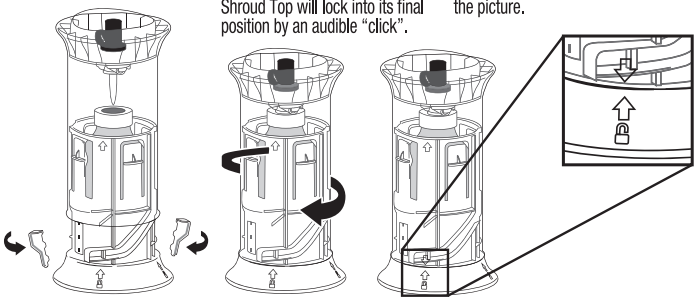
Revised: 09/2021

Instructions for Activation of the Shroud
Before first usage activate the shroud-vial-system as shown in the pictures.
Administer only with a tube-fed safety syringe. Do not use in automatically powered syringes, single-use syringes, or other delivery devices. This product must be used with the quick-fit connector made specifically for use with Micotil (tilmicosin injection) that attaches to the shroud fitting. To obtain a tube-fed safety syringe and quick-fit connector, contact Elanco at 1-800- 428-4441, or your distributor.

Step 1.
Twist the two tamper-evident tabs to break them off the Shroud Base.

Step 2.
Rotate the Shroud Top through a quarter-turn clockwise. The spike will pierce the vial closure, and the Shroud Top will lock into its final position by an audible "click".

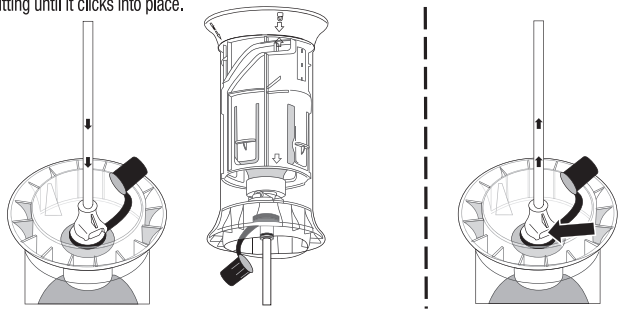
Step 3.
The correct final position can be confirmed by the alignment of the 2 arrows as shown in the picture.



Step 4.
Remove the flexible cap from the fluid connection. Attach the quick-fit connector to tubing if not already attached. Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

Step 5.
Invert the Micotil Shroud, then prime the tube-fed safety syringe following manufacturer's instructions.

Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-fit connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pushing the trigger as shown in the picture, then disconnecting the quick-fit connector from the shroud.



Micotil should not be stored in dosing equipment. Dosing equipment should be disconnected from the shroud after each use. Store product upright. The dosing equipment should be cleaned according to the manufacturer's instructions. Avoid contact with skin, eyes, or mucous membranes.

SAFE HANDLING PRACTICES WHEN USING MICOTIL™ 300 (tilmicosin injection)
Please read this information before you start using Micotil.
This information is a summary and is not intended to take the place of discussions with your veterinarian.
Micotil can only be prescribed by a licensed veterinarian who has information specific to your operation.
You should discuss with your veterinarian how to use Micotil, human warnings associated with the product and recommended safe handling and use practices. For emergency medical information call 1-800-722-0987 or 1-800-428-4441.
If you have any questions about Micotil, talk with your veterinarian or call Elanco at 1-800-428-4441.
To report an adverse drug event contact Elanco at 1-800-428-4441.

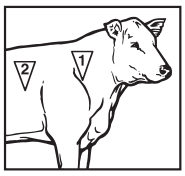
1. WHAT ARE THE POSSIBLE EFFECTS OF ACCIDENTAL HUMAN INJECTION?
Human injections of Micotil have been associated with fatalities. Clinical signs from human exposure include off taste in the mouth, nausea, headache, dizziness, rapid heart rate, chest pain, anxiety, or lightheadedness. Local reactions such as injection site pain, bleeding, swelling or inflammation have been reported.

2. WHAT SHOULD I DO IN THE CASE OF ACCIDENTAL HUMAN INJECTION?
- Immediately seek medical attention.
- Apply ice or cold pack to injection site, while avoiding direct contact with the skin, and transport immediately to a hospital.
- Call 1-800-722-0987 or 1-800-428-4441 for further emergency information.

3. WHAT SHOULD MY PHYSICIAN KNOW IN THE CASE OF ACCIDENTAL HUMAN INJECTION?
- The cardiovascular system is the target of toxicity and should be monitored closely.
- Cardiovascular toxicity may be due to calcium channel blockade.
- Intravenous calcium administration reversed the cardiovascular effects of Micotil in dogs and may provide benefit in patients exhibiting low blood pressure (hypotension) or rapid heart rate (tachycardia).
- Dobutamine improved some of the cardiac function in dogs given Micotil.
- Epinephrine increased the toxicity of Micotil in pigs, resulting in death.
- Propranolol (a beta-adrenergic antagonist) further decreased cardiac function in dogs given Micotil.
- The active ingredient in Micotil is tilmicosin phosphate and persists in tissue for several days.
- Call 1-800-722-0987 or 1-800-428-4441 for further emergency information.

4. WHAT ARE THE PROPER WAYS TO HANDLE AND STORE MICOTIL?
- Store at or below 86°F (30°C), out of direct sunlight, in a safe location, not easily accessible to the general public. Use within 84 days of first puncture. Store upright between product dispensing. Disconnect and clean dosing equipment for storing as per manufacturer's instructions.
- Avoid contact with skin, eyes, or mucous membranes.
- Read, understand, and follow all label use directions.
- Wash hands thoroughly with soap and water after handling.

5. WHAT ARE THE PROPER METHODS FOR ADMINISTERING MICOTIL?
- Properly restrain animals prior to administration.
- Work in a team, or if alone, advise someone of your location and how long you plan to be there.
- For subcutaneous use. Administer only with a tube-fed safety syringe. Do not use in automatically powered syringes, single-use syringes, or other delivery devices. Contact Elanco at 1-800-428-4441, or your distributor, for a tube-fed safety syringe for use with this product.
- Use a 1/2-inch to 5/8-inch, 18- to 16-gauge needle.
- With a single hand on the safety syringe insert the needle subcutaneously, at a top-down angle, while avoiding penetration of underlying muscle.
- For cattle and sheep, injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulders and over the ribs.
- In cattle, administer a single subcutaneous dose of 1.5 to 3.0 mL of Micotil (tilmicosin injection) per 100 lbs of body weight, in either of the two areas noted in the adjacent drawing.
- For beef cattle, Beef Quality Assurance recommends injection site 1, unless this site is inaccessible or places the operator in a potentially dangerous situation.
- Wash hands thoroughly with soap and water after administration.
- Do not administer intravenously (IV) as IV administration will be fatal.
- Intramuscular injection will cause a local reaction, which may result in trim loss.
- Do not inject more than 10 mL per injection site.
- Do not use in lambs less than 15 kg body weight.



6. WHAT ARE SAFE WAYS TO REMOVE AND CHANGE NEEDLES?
- Always follow the manufacturer's instruction of how to safely remove and change needles from the safety syringe.
- Plan for the safe handling and disposal of needles before use.
- Keep the needle capped until ready to use.
- Avoid recapping a used needle.
- To safely remove used needles, use tools appropriate for the specific type of safety syringe. Do not remove a used needle with your fingers.
- Dispose used needles in an appropriate sharps disposal container. Do not overfill sharps containers and do not put your fingers into a sharps container.
- Never place loose needles in household or public trash cans.

PRÁCTICAS DE MANEJO SEGURO CUANDO SE UTILIZA MICOTIL™ 300 (tilmicosina inyectable)
Lea esta información antes de comenzar a utilizar Micotil. Esta información es un resumen y no pretende sustituir que lo analice con su veterinario. Micotil solamente puede ser prescrito por un médico veterinario autorizado que tenga la información específica de su intervención. Usted deberá analizar con su veterinario cómo usar Micotil, las advertencias para seres humanos asociadas con este producto, y las prácticas de manipulación y uso seguras recomendadas. Para información médica de emergencia, llame al 1-800-722-0987 o 1-800-428-4441. Si tiene alguna pregunta acerca de Micotil, hable con su veterinario o llame a Elanco al teléfono 1-800-428-4441. Para reportar algún evento adverso del medicamento, póngase en contacto con Elanco llamando al 1-800-428-4441.

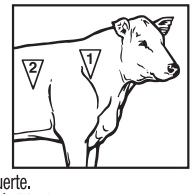
1. ¿CUÁLES SON LOS POSIBLES EFECTOS DE UNA INYECCIÓN ACCIDENTAL EN UN SER HUMANO?
Las inyecciones de Micotil al ser humano se asociaron con fallecimientos. Los signos clínicos de la exposición en seres humanos incluyen sabor desagradable en la boca, náuseas, dolor de cabeza, mareos, latidos rápidos, dolor en el pecho, ansiedad o atontamiento. Se han comunicado reacciones locales como dolor, sangrado, tumefacción o inflamación en el sitio de la inyección.

2. ¿QUÉ DEBO HACER EN CASO DE UNA INYECCIÓN ACCIDENTAL A UN SER HUMANO?
- Busque atención médica inmediatamente.
- Aplique hielo o una compresa fría al sitio de la inyección, evitando el contacto directo con la piel, y transporte al paciente inmediatamente a un hospital.
- Llame al 1-800-722-0987 o al 1-800-428-4441 para obtener más información de emergencia.

3. ¿QUÉ DEBE SABER MI MÉDICO EN CASO DE UNA INYECCIÓN ACCIDENTAL A UN SER HUMANO?
- El sistema cardiovascular es el blanco de la toxicidad y debe monitorearse estrechamente.
- La toxicidad cardiovascular puede deberse a bloqueo de los canales de calcio.
- La administración intravenosa de calcio revirtió los efectos cardiovasculares de Micotil (tilmicosina inyectable) en los perros y puede ofrecer beneficios a los pacientes que presentan presión arterial baja (hipotensión) o latidos rápidos (taquicardia).
- La dobutamina mejoró parcialmente la función cardíaca en los perros que recibieron Micotil.
- La epinefrina aumentó la toxicidad de Micotil en los cerdos, causándoles la muerte.
- Propranolol (un antagonista ß-adrenérgico) disminuyó aún más la función cardíaca en perros tratados con Micotil.
- El ingrediente activo de Micotil es el fosfato de tilmicosina y persiste en los tejidos por varios días.
- Llame al 1-800-722-0987 o al 1-800-428-4441 para obtener más información de emergencia.

4. ¿CUÁLES SON LAS FORMAS ADECUADAS DE MANEJO Y ALMACENAMIENTO DE MICOTIL?
- Almacenar a temperatura de 86 °F (30 °C) o menor, fuera de la luz solar directa, en un sitio seguro que no esté fácilmente accesible al público en general. Usar dentro de los 84 días de la primera punción. Guardar en posición vertical entre cada suministro del producto. Desconectar y limpiar el dispositivo de dosificación para el almacenamiento según las instrucciones del fabricante.
- Evitar el contacto con la piel, los ojos o las membranas mucosas.
- Leer, entender y cumplir con todas las instrucciones para el uso incluidas en la etiqueta.
- Lavarse las manos minuciosamente con agua y jabón después de la manipulación.

5. ¿CUÁLES SON LOS MÉTODOS ADECUADOS PARA LA ADMINISTRACIÓN DE MICOTIL?
- Sujetar a los animales en forma apropiada antes de la administración.
- Trabajar en equipo, o si está solo, informar a alguien de su ubicación y del tiempo que piensa estar allí.
- Para uso subcutáneo. Administrar únicamente con una jeringa de seguridad conectada a un tubo. No utilizar jeringas operadas automáticamente, jeringas de un solo uso u otros dispositivos de aplicación. Contactar a Elanco al 1-800-428-4441, o al distribuidor, para obtener una jeringa de seguridad con tubo para usar con este producto.
- Utilizar una aguja de 1/2 pulgada a 5/8 de pulgada, del calibre 18 a 16.
- Con una sola mano en el dispositivo de dosificación, insertar la aguja subcutáneamente, en un ángulo de arriba hacia abajo, evitando penetrar el músculo subyacente.
- Para bovinos y ovinos se recomienda la inyección subcutánea en la región del cuello. Si no fuese accesible, inyectar debajo de la piel detrás de los hombros y sobre las costillas.
- En bovinos, administrar una sola dosis subcutánea de 1.5 a 3.0 ml de Micotil por cada 100 libras de peso, en cualquiera de las dos áreas marcadas en el dibujo anexo.
- Para el ganado de carne, la Garantía de Calidad de Carne del Bovino recomienda el sitio de inyección 1, a menos que este sitio sea inaccesible o ponga al operador en una situación potencialmente peligrosa.
- Lavarse las manos minuciosamente con agua y jabón después de la administración.



- No administrar por vía intravenosa (IV) ya que la administración IV causará la muerte.
- La inyección intramuscular causará una reacción local, que puede provocar la pérdida de cortes.
- No inyectar más de 10 ml por sitio de inyección.
- No usar en corderos de menos de 15 kg de peso.

6. ¿CUÁLES SON LAS FORMAS SEGURAS DE RETIRAR Y CAMBIAR LAS AGUJAS?
- Seguir siempre las instrucciones del fabricante sobre cómo retirar y cambiar las agujas de la jeringa de seguridad de forma segura.
- Planificar la manipulación y eliminación segura de las agujas antes de su uso.
- Mantener la aguja tapada hasta el momento de su uso.
- Evitar volver a tapar una aguja usada.
- Para retirar de forma segura las agujas usadas, utilizar herramientas apropiadas según el tipo específico de jeringa de seguridad. Se debe evitar retirar una aguja usada con los dedos.
- Desechar las agujas usadas en un contenedor apropiado para la eliminación de objetos punzantes. No llenar en exceso los contenedores de objetos punzantes y no meter los dedos en dichos contenedores.
- No colocar nunca agujas sueltas en los cubos de basura domésticos o públicos.

Elanco™

Component™ E-C with Tylan™

(progesterone and estradiol benzoate and tylosin tartrate implants)

Each implant consists of 100 mg progesterone USP
and 10 mg estradiol benzoate and 29 mg tylosin tartrate

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

IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 100 mg progesterone USP and 10 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain in beef calves 45 days of age and older and weighing up to 400 lbs.

This implant is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant as
safety and effectiveness has not been evaluated.

Do not use in calves less than 45 days of age or veal calves because effectiveness and safety have not been evaluated.

Do not use in animals intended for subsequent breeding,
or in dairy cows.

DIRECTIONS: Administer 1 implant - the entire contents of one cartridge cell (5 pellets) - subcutaneously in the back of the middle third of the ear. Study and carefully follow at all times the "IMPLANTING INSTRUCTIONS" presented below, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 45 days of age, dairy calves, and veal calves. Do not use in bull calves intended for reproduction. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS: Not for use in humans.
Keep out of reach of children.

Restricted Drug (California) - Use Only as Directed

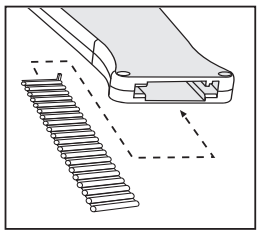
ANIMAL SAFETY WARNINGS: Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C with Tylan Implants.

WARNINGS: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

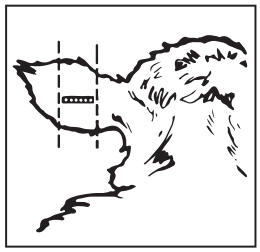
IMPLANTING INSTRUCTIONS:

Loading the Implanter
Load the implanter following the instructions supplied with each implanter.

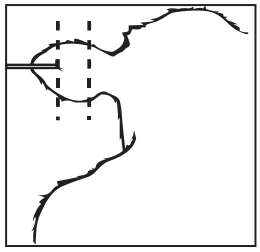


Restrain the Animal
Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint.

Prepare the Implant Site
Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton or brush which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



Where to Implant
The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle
With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

Implant the Pellets
After inserting the needle fully in the correct implant position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may lead to undesirable side effects such as bulling, rectal and vaginal prolapse, etc., as noted in the WARNINGS.

STORAGE CONDITIONS: Store at controlled room temperature 15° to 30°C (59° to 86°F) DO NOT refrigerate – avoid excessive heat and humidity. Discard open foil pouches.

Approved by FDA under NADA # 110-315

Manufactured by a non-sterilizing process.

Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

Distributed by Elanco US Inc., Greenfield, IN 46140, USA

Tylosin: Product of United Kingdom

Revised: June 2023

Elanco™

Component™ TE-200 with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

FOR GROWING BEEF STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

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

20 dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-200 with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 11 pellets consists of 10 pellets containing a total of 200 mg of trenbolone acetate and 20 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated.

Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

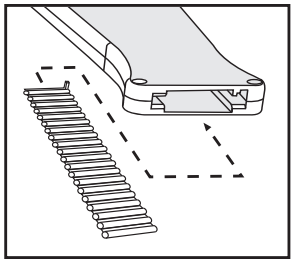
Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.

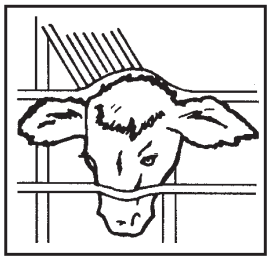


Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

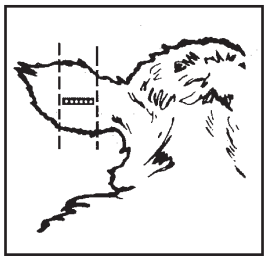
Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



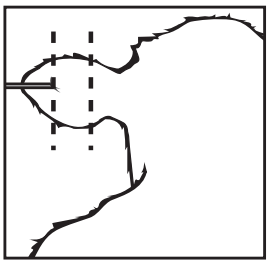
Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets

After inserting the needle fully in the correct implant position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Storage Conditions

Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.

Use before the expiration date printed on the foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-346

Manufactured by a non-sterilizing process.

Component TE-200 with Tylan (trenbolone acetate and estradiol and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

Distributed by Elanco US Inc.,
Greenfield, IN 46140, USA

Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

April 2023

Elanco™

Component™ TE-G with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

FOR GROWING BEEF STEERS AND HEIFERS ON PASTURE (Stocker, Feeder, and Slaughter)

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

20 dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION:

Each cartridge belt holds 20 doses of Component TE-G with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 3 pellets consists of 2 pellets containing a total of 40 mg of trenbolone acetate and
8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE:

For increased rate of weight gain in growing beef steers and heifers on pasture (stocker, feeder, and slaughter).
Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following re-implantation have not
been evaluated.
Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.
Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING:

This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows. Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS:

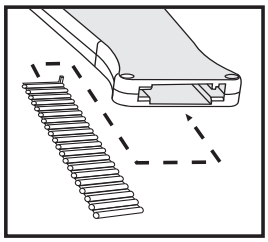
Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

Prepare the Implant Site

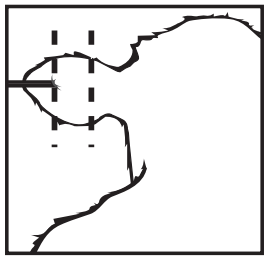
Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.

Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets

After inserting the needle fully in the correct position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of the single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Storage Conditions

Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.
Use before the expiration date printed on foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-221

Manufactured by a non-sterilizing process.

Component TE-G with Tylan is covered by U.S. Patent No. 5,874,098

Distributed by Elanco US Inc,
Greenfield, IN 46140, USA

Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

April 2023

Elanco™

Component™ TE-IH with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

FOR GROWING BEEF HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

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

20-dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-IH with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter.

Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef heifers fed in confinement for slaughter. Safety and effectiveness following re-implantation have not been evaluated.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.

Do not use in animals intended for subsequent breeding, or in dairy cows.

NOTE: Studies have demonstrated that administration of Component TE-IH can result in decreased marbling scores when compared to non-implanted heifers.

WARNING: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).
The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.
Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.
Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

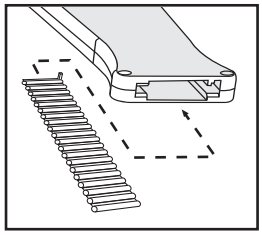
Not for use in humans. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS:

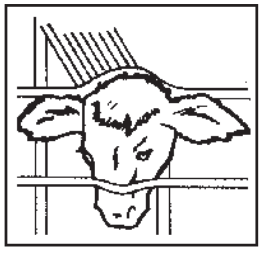
Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

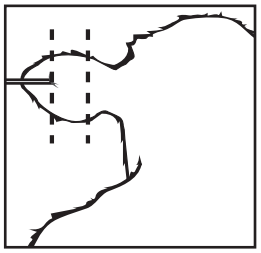


Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear illustrated in the drawing.
The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site.
Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

Implant the Pellets

After inserting the needle fully in the correct position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Storage Conditions

Store unopened product at or below 25°C (77°F).
Avoid excessive heat and humidity.
Use before the expiration date printed on the foil pouch.
Discard open foil pouches.

Approved by FDA under ANADA # 200-346

Manufactured by a non-sterilizing process.

Component TE-IH with Tylan (trenbolone acetate and estradiol and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

Distributed by Elanco US Inc.,
Greenfield, IN 46140, USA

Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973.
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

April 2023

Elanco™

Component™ TE-IS with Tylan™

(trenbolone acetate and estradiol and tylosin tartrate implants)

FOR GROWING BEEF STEERS FED IN CONFINEMENT FOR SLAUGHTER

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

20-dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-IS with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 16 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter.
Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter.
Safety and effectiveness following re-implantation have not been evaluated.
Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.
Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING:
This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).
The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

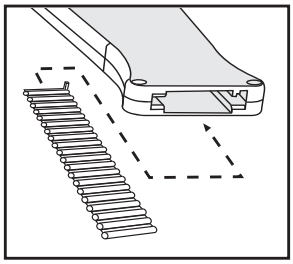
Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.
Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.
Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.
Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS
Not for human use. Keep out of reach of children.

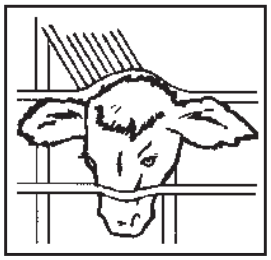
Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS:
Loading the Implanter
Load the implanter following the instructions supplied with each implanter.

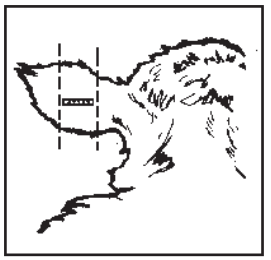


Restrain the Animal
Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint.
When implanting horned cattle, better control is obtained with additional use of nose tongs.

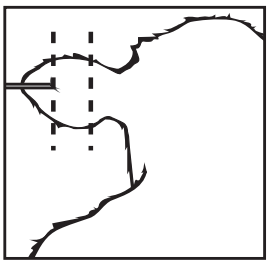
Prepare the Implant Site
Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



Where to Implant
The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear illustrated in the drawing.
The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site.
Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle
With one hand firmly grasp the ear.
With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets
After inserting the needle fully in the correct implant position squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Storage Conditions
Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.
Use before the expiration date printed on the foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-221

Manufactured by a non-sterilizing process.

Component TE-IS with Tylan is covered by U.S. Patent No. 5,874,098

Distributed by Elanco US Inc., Greenfield, IN 46140, USA

Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

April 2023

Elanco™ AH0206

Tylan™ 200 Injection™

250 mL

(tylosin injection)

200 mg per mL

For Use In Cattle and Swine Only

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

An Antibiotic

Indications: In Beef Cattle and Non-lactating Dairy Cattle, Tylan 200 Injection 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, Tylan 200 Injection 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 percent propylene glycol with 4 percent benzyl alcohol and water for injection.

ADMINISTRATION AND DOSAGE: Tylan 200 Injection is administered intramuscularly.

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 Tylan 200 Injection 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 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 Tylan 50 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.

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 or below 25°C (77°F).

Approved by FDA under NADA # 012-965

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Manufactured for: Elanco US Inc.
Greenfield, IN 46140, USA

Product of Ireland

Elanco™ AH0206

Tylan™ 200 Inyectable™

250 mL

(tilosina inyectable)

200 mg por ml

Para uso exclusivo en ganado vacuno y cerdos

PRECAUCIÓN: Las leyes federales establecen que el uso de este fármaco se restrinja a veterinarios con licencia o bajo la indicación de estos.

Un antibiótico:

Indicaciones: En ganado vacuno y vacas lecheras no lactantes, Tylan 200 Inyectable se indica para el tratamiento del complejo respiratorio bovino (fiebre de embarque, neumonía), generalmente asociado con *Pasteurella multicoda* y *Arcanobacterium pyogenes*, pietín (pododermatitis necrótica), difteria de los terneros provocada por *Fusobacterium necrophorum* y metritis provocada por *Arcanobacterium pyogenes*. En cerdos, Tylan 200 Inyectable se indica para el tratamiento de artritis en cerdos provocada por *Mycoplasma hyosynoviae*, neumonía porcina causada por *Pasteurella* spp., erisipelas porcinas provocadas por *Erysipelothrix rhusiopathiae*, disentería porcina asociada con *Treponema hyodysenteriae* cuando es tratada con el medicamento apropiado a través del alimento y/o el agua para beber.

Cada ml contiene 200 mg de actividad de tilosina (como tilosina base) en propilenglicol al 50 por ciento, alcohol bencílico al 4 por ciento y agua para inyección.

POSOLOGÍA Y ADMINISTRACIÓN: Tylan 200 Inyectable se administra por vía intramuscular.

GANADO VACUNO Y VACAS LECHERAS NO LACTANTES—Inyectar por vía intramuscular 8 mg por libra de peso corporal una vez al día (1 ml cada 25 libras). El tratamiento debe continuarse durante 24 horas luego de la remisión de los signos de la enfermedad sin extenderse más de 5 días. No aplicar más de 10 ml por lugar de inyección.

CERDOS—Inyectar por vía intramuscular 4 mg por libra de peso corporal (1 ml cada 50 libras) dos veces al día. El tratamiento debe continuarse durante 24 horas luego de la remisión de los signos de la enfermedad sin extenderse más de 3 días. No aplicar más de 5 ml por lugar de inyección.

Leer todas las instrucciones adjuntas antes de usar.

PRECAUCIÓN:

No mezclar la inyección Tylan 200 con otras soluciones inyectables ya que esto puede ocasionar la precipitación de los principios activos.

ADVERTENCIAS:

ESTE PRODUCTO NO DEBE UTILIZARSE EN SERES HUMANOS. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.

Pueden ocurrir reacciones adversas, incluidos shock y muerte, en caso de sobredosis en crías de cerdos.

No administrar la inyección a cerdos que pesen menos de 25 libras (0.5 ml) con la jeringa común. Se recomienda usar la inyección Tylan 50 en cerdos que pesen menos de 25 libras.

No administrar a caballos u otros equinos. La inyección de tilosina en equinos ha resultado mortal.

ADVERTENCIA ACERCA DE RESIDUOS: Ganado porcino: el ganado porcino previsto para consumo humano no se debe faenar durante los 14 días posteriores al último uso de este producto farmacológico.

ADVERTENCIA ACERCA DE RESIDUOS: Ganado bovino: el ganado bovino previsto para consumo humano no se debe faenar durante los 21 días posteriores al último uso de este producto farmacológico. Este producto farmacológico no está aprobado para su uso en ganado bovino lechero hembra de 20 meses de edad o más, incluidas las vacas lecheras secas. El uso en este ganado bovino puede producir residuos farmacológicos en la leche y/o en los terneros nacidos de estas vacas. Este producto no está aprobado para el uso en terneros que se procesarán para carne de ternera. No se ha establecido un período de retiro del fármaco en terneros prerrumiantes.

Si se suministra agua para beber con tilosina como tratamiento de seguimiento para la disentería porcina, el animal debe recibir posteriormente alimento que contenga entre 40 y 100 gramos de tilosina por tonelada durante 2 semanas para garantizar la depleción de los residuos de tejidos.

Almacenar a 25 °C (77 °F) o menos.

Aprobado por la FDA bajo NADA # 012-965

Para obtener información adicional sobre cómo informar experiencias adversas de medicamentos para medicamentos animales, comuníquese con la FDA al 1-888-FDA-VETS o http://www.fda.gov/reportanimalae.

Fabricado por: Elanco US Inc.
Greenfield, IN 46140, USA

Producto de Irlanda

Elanco™ AH0206

Tylan™ 200 Injection™

Professional Size
500 mL

(tylosin injection)

200 mg per mL

For Use In Cattle and Swine Only

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

An Antibiotic

Use automatic syringe equipment only

Indications: In Beef Cattle and Non-lactating Dairy Cattle, Tylan 200 Injection 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, Tylan 200 Injection 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 percent propylene glycol with 4 percent benzyl alcohol and water for injection.

ADMINISTRATION AND DOSAGE: Tylan 200 Injection is administered intramuscularly.

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 Tylan 200 Injection 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 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 Tylan 50 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.

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 or below 25°C (77°F).

Approved by FDA under NADA # 012-965

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Manufactured for: Elanco US Inc.
Greenfield, IN 46140, USA
Product of Ireland

Elanco™ AH0206

Tylan™ 200 Inyectable™

Tamaño profesional
500 ml

(tilosina inyectable)

200 mg por ml

Para uso exclusivo en ganado vacuno y cerdos

PRECAUCIÓN: Las leyes federales establecen que el uso de este fármaco se restrinja a veterinarios con licencia o bajo la indicación de estos.

Un antibiótico

Utilizar sólo equipos automáticos de jeringas

Indicaciones: En ganado vacuno y vacas lecheras no lactantes, Tylan 200 Inyectable se indica para el tratamiento del complejo respiratorio bovino (fiebre de embarque, neumonía), generalmente asociado con *Pasteurella multocida* y *Arcanobacterium pyogenes*, pietín (pododermatitis necrótica), difteria de los terneros provocada por *Fusobacterium necrophorum* y metritis provocada por *Arcanobacterium pyogenes*.

En cerdos, Tylan 200 Inyectable se indica para el tratamiento de artritis en cerdos provocada por *Mycoplasma hyosynoviae*, neumonía porcina causada por *Pasteurella* spp., erisipelas porcinas provocadas por *Erysipelothrix rhusiopathiae*, disentería porcina asociada con *Treponema hyodysenteriae* cuando es tratada con el medicamento apropiado a través del alimento y/o el agua para beber.

Cada ml contiene 200 mg de actividad de tilosina (como tilosina base) en propilenglicol al 50 por ciento, alcohol bencílico al 4 por ciento y agua para inyección.

POSOLOGÍA Y ADMINISTRACIÓN: Tylan 200 Inyectable se administra por vía intramuscular.

GANADO VACUNO Y VACAS LECHERAS NO LACTANTES—Inyectar por vía intramuscular 8 mg por libra de peso corporal una vez al día (1 ml cada 25 libras). El tratamiento debe continuarse durante 24 horas luego de la remisión de los signos de la enfermedad sin extenderse más de 5 días. No aplicar más de 10 ml por lugar de inyección.

CERDOS—Inyectar por vía intramuscular 4 mg por libra de peso corporal (1 ml cada 50 libras) dos veces al día. El tratamiento debe continuarse durante 24 horas luego de la remisión de los signos de la enfermedad sin extenderse más de 3 días. No aplicar más de 5 ml por lugar de inyección.

Leer todas las instrucciones adjuntas antes de usar.

PRECAUCIÓN:

No mezclar la inyección Tylan 200 con otras soluciones inyectables ya que esto puede ocasionar la precipitación de los principios activos.

ADVERTENCIAS:

ESTE PRODUCTO NO DEBE UTILIZARSE EN SERES HUMANOS. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.

Pueden ocurrir reacciones adversas, incluidos shock y muerte, en caso de sobredosis en crías de cerdos.

No administrar la inyección a cerdos que pesen menos de 25 libras (0.5 ml) con la jeringa común. Se recomienda usar la inyección Tylan 50 en cerdos que pesen menos de 25 libras.

No administrar a caballos u otros equinos. La inyección de tilosina en equinos ha resultado mortal.

ADVERTENCIA ACERCA DE RESIDUOS: Ganado porcino: el ganado porcino previsto para consumo humano no se debe faenar durante los 14 días posteriores al último uso de este producto farmacológico.

ADVERTENCIA ACERCA DE RESIDUOS: Ganado bovino: el ganado bovino previsto para consumo humano no se debe faenar durante los 21 días posteriores al último uso de este producto farmacológico. Este producto farmacológico no está aprobado para su uso en ganado bovino lechero hembra de 20 meses de edad o más, incluidas las vacas lecheras secas. El uso en este ganado bovino puede producir residuos farmacológicos en la leche y/o en los terneros nacidos de estas vacas. Este producto no está aprobado para el uso en terneros que se procesarán para carne de ternera. No se ha establecido un período de retiro del fármaco en terneros prerrumiantes.

Si se suministra agua para beber con tilosina como tratamiento de seguimiento para la disentería porcina, el animal debe recibir posteriormente alimento que contenga entre 40 y 100 gramos de tilosina por tonelada durante 2 semanas para garantizar la depleción de los residuos de tejidos.

Almacenar a 25 °C (77 °F) o menos.

Aprobado por la FDA bajo NADA # 012-965

Para obtener información adicional sobre cómo informar experiencias adversas de medicamentos para medicamentos animales, comuníquese con la FDA al 1-888-FDA-VETS o http://www.fda.gov/reportanimalae.

Fabricado por: Elanco US Inc.
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