



2024 Cattle Loyalty Veterinary Program

Feb. 1, 2024 – Jan. 31, 2025

Right for cattle. Right by you.

ElancoTM

Right for cattle. Right by you.

At Elanco, we understand veterinarians are key to beef and dairy cattle performance. We're proud to offer a loyalty program that supports the performance of your business.

Program level	Portfolio purchases	Rebate
Tier 1	\$30,000	4%
Tier 2	\$50,000	5%
Tier 3	\$75,000	6%
Tier 4	\$100,000	7%
Tier 5	\$200,000	8%

Eligible cattle products

Cattle Vaccines

- Bovine Pili Shield®
- Fusogard®
- Lepto Shield®
- Master Guard®
- NUPLURA® PH
- 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® E-C with Tylan® (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)
- Loncor® (florfenicol)
- Zelate® DNA Immunostimulant

Insecticides

- Agita® 10 WG
- Beetle Shield® 6
- Catron® IV
- Clean-Up™ II Pour-On Insecticide with IGR
- Conquest™ Insecticide
- CyLence® Ultra Pest Control Concentrate
- CyLence® Ultra Premise Spray
- CyLence® Pour-On Insecticide
- Elector® PSP
- Neporex® 2 SG
- All Permethrin® 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

Eligibility

This Program is exclusive for large animal and mixed practice veterinary clinics. Participants confirm that the products will be used for patients under their care. Products should be dispensed by veterinary clinics under a legitimate veterinarian-client-patient relationship as defined by the American Veterinary Medical Association (AVMA). This Program is not intended for buying groups. Elanco reserves the right, in its sole but reasonable discretion, to designate or refuse to designate any such entity as a buying group under the Program. Elanco's determination shall be final.

Those accounts enrolled in corporate agreements, Reseller agreements, competitive bids, swine agreements, non-profit organizations and government entities are ineligible to participate in this Program. To qualify for payment, participants must comply with all terms within this Program and any other applicable terms related to this Program. Offer is void where prohibited by law.

Enrollment terms

- All participants in the 2023 Cattle Loyalty Vet Program that achieved Tier 1 or higher and reached a minimum of \$30,000 qualified purchases by December 31, 2023 are automatically enrolled for the 2024 program beginning February 1, 2024. The 2024 tier level enrollment is defined by purchases made in 2023.
- Within 60 days after the end of each calendar quarter, Elanco will perform a "true-up" reconciliation report.
 - If the foregoing reconciliation report shows the Program Participant's EDI purchases does not meet their enrollment tier applicable sales for such quarter, Elanco retains the right to withhold rebate payments until the difference owed to Elanco is fully reconciled.
 - Program participants who exceed their enrollment tier by year end will be true-up in their Q4 rebate payment retroactive to February 1, 2024.
- New participants who did not achieve Tier 1 status and reach a minimum of \$30,000 by December 31, 2023 must verify enrollment information when contacted by Elanco prior to any rebate check being mailed.
- Purchases will be eligible for rebate retroactive to the first day of the year.

Proof of purchase

- Products must be purchased from an Elanco authorized distributor and/or Elanco Reseller between February 1, 2024 and January 31, 2025.
- Only product purchases billed to qualifying, enrolled customers are eligible. In the case of multiple qualifying bill-to locations, a single payment will be made to the primary billing account.
- Only sales reported to Elanco via EDI will be used for Program tracking and payment.
- Eligible purchases must be invoiced by January 31, 2025.

Rebate payments

- Veterinarians can earn rebates payable quarterly on all qualifying Elanco product purchases from an authorized Elanco distributor and/or Elanco Reseller upon satisfactory Program participation.
- A minimum purchase of \$30,000 on qualifying products must be made to receive a rebate. A customer must earn a minimum of a \$100 rebate during the Program period to receive a check.
- All product returns will be applied toward the subsequent Program payout period.
- Elanco will be responsible for calculating rebates based on EDI purchases.
- Elanco reserves the right to audit EDI data. If found to be inaccurate, Elanco has the right to withhold rebate earnings.
- Products not listed do not contribute to the Cattle Loyalty Program.

Disclaimers

- Elanco reserves the right to add product offerings during the Program period.
- Elanco reserves the right to decline the enrollment of any participant, refuse the payment of any rebates or recalculate any previous or future payments at their sole discretion. Elanco further reserves the right to modify, expand, reduce, extend or cancel the Program upon 30 days written notice to customers in the Program.
- Participation in this program does not imply or guarantee supply of Elanco products.

For more information regarding this rebate program and enrollment, contact your Elanco Animal Health representative or call 800-364-2014.

Elanco Cattle Loyalty: A program to grow with your business and advance the health of cattle.

- Increase your rebate incentives as your purchases with Elanco grow.
- Grow your business further within the Cattle Loyalty Program through promotional funds that support business development activities.
- Take advantage of products, services and complimentary veterinary consultation to support healthier cattle, improve economic performance and advance the operational sustainability of your business.

To learn more or to enroll in the program, contact your Elanco sales representative.

At Elanco's core is our commitment to healthy animals and the opportunities that provides for the people who care for them. This approach means helping producers, veterinarians and nutritionists continue to advance animal science with tools that manage key health challenges so cattle can thrive.

For more information about Elanco, please visit [Elanco.com](https://www.elanco.com)

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*.

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 Loncor are sold by Elanco or its affiliates and are not Bayer products. The Baytril and Loncor trademarks are owned by Bayer and used under license. Agita, Beetle Shield, Bovine Pili Shield, Catron IV, Clean-Up, Conquest, Component, Compudose, Corathon, Cydectin, CyLence, CyLence Ultra, Elector, Encore, Fusogard, Increxxa, Lepto Shield, Master Guard, Micotil, Neporex, NUPLURA, Patriot, Permethrin, Pinkeye Shield, QuickBayt, Rabon, ReproSTAR, Scour Bos, Somnu Shield, Titanium, Tylan, Vib Shield, Vira Shield, Zelnate, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates. ©2023 Elanco or its affiliates. PM-US-23-2423

Right for cattle. Right by you.

Elanco

TM

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

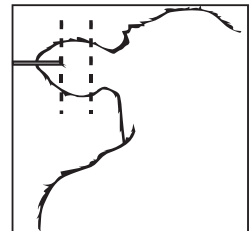
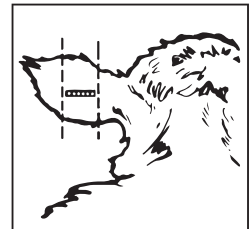
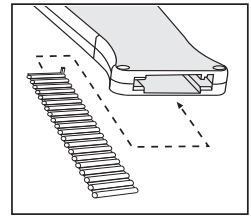
Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

© 2023 Elanco or its affiliates

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.

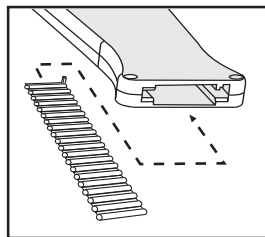
IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.

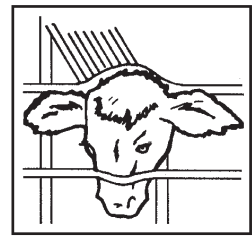
Restrain the Animal

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.



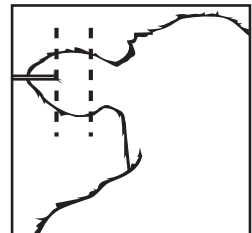
Where to Implant

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

Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

© 2023 Elanco or its affiliates

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

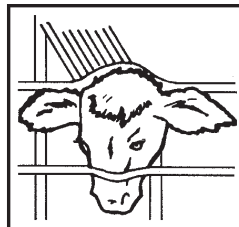
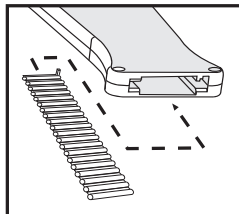
Load the implanter following the instructions supplied with each implanter.

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.



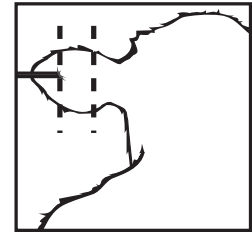
Where to Implant

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

Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

© 2023 Elanco or its affiliates

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

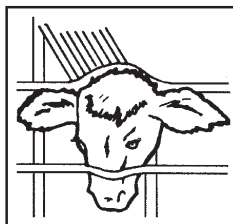
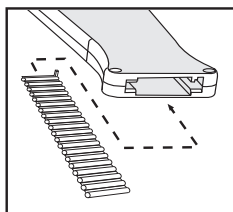
Load the implanter following the instructions supplied with each implanter.

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

Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

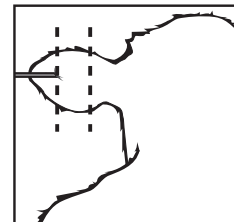
© 2023 Elanco or its affiliates

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:

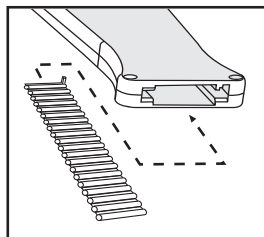
Loading the Implanter

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

Component, Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

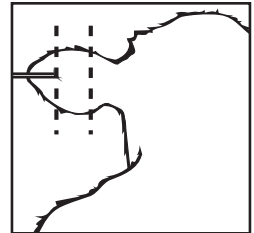
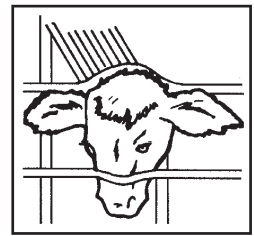
© 2023 Elanco or its affiliates

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™
Micotil™ 300
 250 mL™
(tilmicosin injection)

300 mg tilmicosin, USP as tilmicosin phosphate per mL
 For Subcutaneous Use in Cattle Only

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.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Before using Micotil, please consult the product insert, a summary of which follows:

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

Approved by FDA under NADA # 140-929

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.

Dosage and Administration: Follow instructions for activation of the shroud before first usage. Inject Subcutaneously in Cattle Only. See Safe Handling Practices, Contraindications, and Warnings prior to use. In cattle, administer a single subcutaneous dose of 10 to 20 mg/kg body weight (1 to 2 mL/30 kg or 1.5 to 3 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 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. See product insert for complete dosing and administration information.

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. Intravenous injection in cattle will be fatal. Do not administer to animals other than cattle. 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.

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.

Precautions: The effects of tilmicosin on bovine 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.

Storage Conditions: Store at or below 86 °F (30 °C). Protect from direct sunlight. Use within 84 days of first puncture. Date of first puncture: _____ To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

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. β-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.

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

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.

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

Micotil, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

© 2023 Elanco or its affiliates. PM-US-23-1966

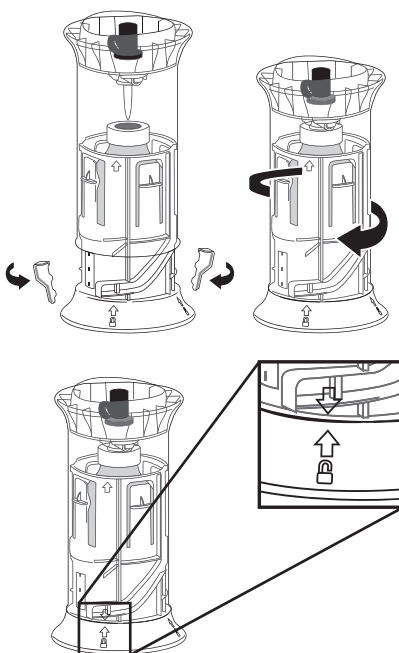
Instructions for Activation of the Shroud

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".

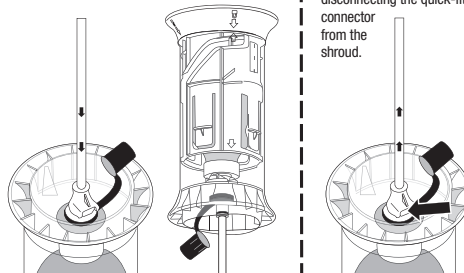
Step 3. The correct final position can be confirmed by the alignment of the 2 arrows as shown in the picture.



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

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?

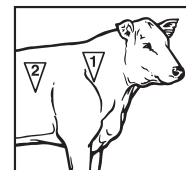
- The cardiovascular system is the target of toxicity and should be monitored closely.
- Cardiovascular toxicity may be due to calcium channel blockade.
- Intravenous calcium administration reversed the cardiovascular effects of Micotil in dogs and may provide benefit in patients exhibiting low blood 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, 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.



**100 mg/mL Antimicrobial
Injectable Solution**

For Subcutaneous Use In Beef Cattle And Non-Lactating Dairy Cattle
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.

Before Using Baytril 100, please consult the complete product insert, a summary of which follows:

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.

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), 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 $\geq 30^{\circ}\text{F}$ during transportation.
- A $\geq 30^{\circ}\text{F}$ 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.

See product insert for complete dosing and administration information.

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.

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 reproductive performance, pregnancy and lactation have not been adequately determined.

Subcutaneous injection in cattle 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 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>.

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.

STORAGE CONDITIONS: Protect from direct sunlight. Do not refrigerate or freeze. Store at 20-30°C (68-86°F), excursions permitted up to 40°C (104°F). 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

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 is sold by Elanco or its affiliates and is not a product of Bayer.
The product name Baytril is owned by Bayer and used under license.
Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.
© 2022 Elanco or its affiliates. PM-US-23-1616

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



Loncor™ 300

(florfenicol)



300 mg/mL Injectable Solution

For intramuscular and subcutaneous use in beef and non-lactating dairy cattle only
Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal

CAUTION

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

DESCRIPTION

Loncor™ 300 Injectable Solution is a solution of the synthetic antibiotic florfenicol. Each milliliter of sterile LONCOR™ 300 contains 300 mg of florfenicol, 250 mg N-Methyl-2-pyrrolidone, 150 mg propylene glycol, and polyethylene glycol qs.

INDICATIONS

LONCOR™ 300 is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

DOSE AND ADMINISTRATION

For treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon (foot rot): LONCOR™ 300 should be administered by intramuscular injection to cattle at a dose rate of 20 mg/kg body weight (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, LONCOR™ 300 can be administered by a single subcutaneous (SC) injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

NOTE: Intramuscular injection may result in local tissue reaction which persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

For control of respiratory disease in cattle at high risk of developing BRD: LONCOR™ 300 should be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

LONCOR™ 300 DOSAGE GUIDE

ANIMAL WEIGHT (lbs)	IM LONCOR 300 DOSAGE 3.0 mL/100 lb Body Weight (mL)	SC LONCOR 300 DOSAGE 6.0 mL/100 lb Body Weight (mL)
100	3.0	6.0
200	6.0	12.0
300	9.0	18.0
400	12.0	24.0
500	15.0	30.0
600	18.0	36.0
700	21.0	42.0
800	24.0	48.0
900	27.0	54.0
1000	30.0	60.0

RECOMMENDED INJECTION LOCATION



Do not inject more than 10 mL per injection site.

Clinical improvement should be evident in most treated subjects within 24 hours of initiation of treatment. If a positive response is not noted within 72 hours of initiation of treatment, the diagnosis should be re-evaluated.

CONTRAINDICATIONS

Do not use in animals that have shown hypersensitivity to florfenicol.

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

This product contains materials that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothing. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Consult a physician if irritation persists. Accidental injection of this product may cause local irritation. Consult a physician immediately. The Safety Data Sheet (SDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the SDS, call 1-800-422-9874.

PRECAUTIONS

Not for use in animals intended for breeding purposes. The effects of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy. Intramuscular injection may result in local tissue reaction which persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

RESIDUE WARNINGS

Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. This 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 calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

ADVERSE REACTIONS

Inappetence, decreased water consumption, or diarrhea may occur transiently following treatment. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco at 1-800-422-9874. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

90199669

CLINICAL PHARMACOLOGY

The pharmacokinetic disposition of florfenicol was evaluated in feeder calves following single intramuscular (IM) administration at the recommended dose of 20 mg/kg body weight. Florfenicol was also administered intravenously (IV) to the same cattle in order to calculate the volume of distribution, clearance, and percent bioavailability¹ (Table 1).

TABLE 1. Pharmacokinetic Parameter Values for Florfenicol Following IM Administration of 20 mg/kg Body Weight to Feeder Calves (n=10).

Parameter	Median	Range
C _{max} (µg/mL)	3.07*	1.43 - 5.60
T _{max} (hr)	3.33	0.75 - 8.00
T _{1/2} (hr)	18.3**	8.30 - 44.0
AUC (µg•min/mL)	4242	3200 - 6250
Bioavailability (%)	78.5	59.3 - 106
Vd _{ss} (L/kg)***	0.77	0.68 - 0.85
Cl _t (mL/min/kg)***	3.75	3.17 - 4.31

* harmonic mean

** mean value

*** following IV administration

C_{max} Maximum serum concentration

T_{max} Time at which C_{max} is observed

T_{1/2} Biological half-life

AUC Area under the curve

Vd_{ss} Volume of distribution at steady state

Cl_t Total body clearance

Florfenicol was detectable in the serum of most animals through 60 hours after intramuscular administration with a mean concentration of 0.19 µg/mL. The protein binding of florfenicol was 12.7%, 13.2%, and 18.3% at serum concentrations of 0.5, 3.0, and 16.0 µg/mL, respectively.

MICROBIOLOGY

Florfenicol is a synthetic, broad-spectrum antibiotic active against many Gram-negative and Gram-positive bacteria isolated from domestic animals. It acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Florfenicol is generally considered a bacteriostatic drug, but exhibits bactericidal activity against certain bacterial species. *In vitro* studies demonstrate that florfenicol is active against the bovine respiratory disease (BRD) pathogens *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and that florfenicol exhibits bactericidal activity against strains of *M. haemolytica* and *H. somni*. Clinical studies confirm the efficacy of florfenicol against BRD as well as against commonly isolated bacterial pathogens in bovine interdigital phlegmon including *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

The minimum inhibitory concentrations (MICs) of florfenicol for BRD organisms were determined using isolates obtained from natural infections from 1990 to 1993. The MICs for interdigital phlegmon organisms were determined using isolates obtained from natural infections from 1973 to 1997 (Table 2).

TABLE 2. Florfenicol Minimum Inhibitory Concentration (MIC) Values* of Indicated Pathogens Isolated From Natural Infections of Cattle.

Indicated pathogens	Year of isolation	Isolate Numbers	MIC ₅₀ ** (µg/mL)	MIC ₉₀ ** (µg/mL)
<i>Mannheimia haemolytica</i>	1990 to 1993	398	0.5	1
<i>Pasteurella multocida</i>	1990 to 1993	350	0.5	0.5
<i>Histophilus somni</i>	1990 to 1993	66	0.25	0.5
<i>Fusobacterium necrophorum</i>	1973 to 1997	33	0.25	0.25
<i>Bacteroides melaninogenicus</i>	1973 to 1997	20	0.25	0.25

* The correlation between the *in vitro* susceptibility data and clinical effectiveness is unknown.

** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

ANIMAL SAFETY

A 10X safety study was conducted in feeder calves. Two intramuscular injections of 200 mg/kg were administered at a 48-hour interval. The calves were monitored for 14 days after the second dose. Marked anorexia, decreased water consumption, decreased body weight, and increased serum enzymes were observed following dose administration. These effects resolved by the end of the study. A 1X, 3X, and 5X (20, 60, and 100 mg/kg) safety study was conducted in feeder calves for 3X the duration of treatment (6 injections at 48-hour intervals). Slight decrease in feed and water consumption was observed in the 1X dose group. Decreased feed and water consumption, body weight, urine pH, and increased serum enzymes, were observed in the 3X and 5X dose groups. Depression, soft stool consistency, and dehydration were also observed in some animals (most frequently at the 3X and 5X dose levels), primarily near the end of dosing.

A 43-day controlled study was conducted in healthy cattle to evaluate effects of florfenicol administered at the recommended dose on feed consumption. Although a transient decrease in feed consumption was observed, florfenicol administration had no long-term effect on body weight, rate of gain, or feed consumption.

STORAGE INFORMATION

Store below 30°C (86°F).

Once opened, use contents within 6 months.

The solution is light yellow to straw colored. Color does not affect potency.

HOW SUPPLIED

Loncor™ 300 is packaged in 250 mL and 500 mL glass sterile multiple-dose vials.

REFERENCE

1. Lobell RD, Varma KJ, et al. Pharmacokinetics of florfenicol following intravenous and intramuscular doses to cattle. *J Vet Pharmacol Therap.* 1994; 17:253-258.

Made in China

LV2102

© 2021 Elanco or its affiliates.

Approved by FDA under ANADA # 200-582

February, 2021

LONCOR™ 300

LONCOR, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

Elanco US Inc

Shawnee, KS 66216 U.S.A.

Elanco

Elanco™

Tylan™ 200 Injection

TM
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).

Tylan, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

© 2023 Elanco or its affiliates. PM-US-23-1624

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