Elanco

Micotil®
Tilmicosin Injection™

ADMINISTRATION GUIDE

After 30 years on the market, Elanco remains committed to evolving how Micotil® can be safely handled so producers and veterinarians can continue to realize its benefits for treating and controlling BRD.

Indications: Micotil 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 *M. haemolytica*.

Dosage and administration: Inject subcutaneously only. 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.). Do not inject more than 10 mL per injection site.

Residue warning: Micotil has a withdrawal time of 42 days, regardless of dose.

SAFE
SELF ANIMAL FOOD ENVIRONMENT
SAFE HANDLING AND USE OF INJECTABLE PRODUCTS

Right for cattle. Right by you.

Elanco™

PREPARING TO ADMINISTER

Micotil is supplied with a protective, ergonomic case called a shroud. For your safety, the shroud cannot be removed. Micotil should only be administered with a tube-fed safety syringe. Use the following instructions to prepare the shroud and safety syringe for administration.

PREPARE THE SHROUD

1. Gather materials to administer Micotil. Materials needed include the 250 ml product bottle encased in the protective shroud, a tube-fed safety syringe and an appropriately sized needle for subcutaneous injection.
2. Locate the two tamper-evident tabs at the base of the shroud. Twist and break them off.
3. Rotate the shroud top a quarter-turn clockwise. The top will lower and the spike will pierce the vial closure. An audible click should be heard as the shroud top locks into its final position.
4. Remove the flexible cap and push the quick-fit connector downwards onto the shroud fitting until it clicks into place. At this point, the tube should already be connected to your safety syringe.
5. Invert the shroud to prime the safety syringe.

SYRINGE PROVIDES ENHANCED USER SAFETY

Micotil is supplied with a safety syringe containing patented technology with self-tenting and needle-guard features. The syringe reduces the chance of accidental self-injection and withstands the most challenging environments at feedyards and stocker operations. Prior to injection, the trigger must be pulled and then the syringe pushed against the calf. Both actions must be performed for the product to be administered.

To obtain more information about this syringe, or to receive one, please contact your veterinarian, distributor or Elanco representative.

PRIME THE SAFETY SYRINGE

1. Set the dose adjuster to the maximum setting.
2. Grasp the safety syringe and depress the trigger with the forefinger.
3. Using your spare hand, pull the needle guard back and hold in this retracted position for the remainder of the priming procedure.
4. Squeeze and release the safety syringe handles repeatedly to draw product through the tube. Once the product enters the barrel, carefully squeeze handles to expel remaining air. Tilt the syringe upward to help get as much air out of the barrel as possible. Use caution to avoid spillage of product.
5. Allow the needle guard to return forward and release trigger.
6. Set the dose adjuster to the required setting.

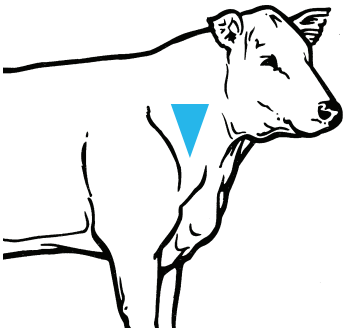
ATTACH THE NEEDLE

1. Remove the needle guard by grasping the safety syringe and press needle guard release tab with your thumb. Remove the guard with your other hand.
2. Keep your thumb and fingers on the metal slide so they are well clear of the trigger. Fit the appropriately sized needle onto the tip and rotate clockwise to engage threads. Avoid over tightening the needle.
3. Replace the needle guard by aligning it with the metal slide and push so that the release tab of the needle guard clips into place.

AFTER ADMINISTRATION

Careful handling and clean-up following administration is important for your safety and the continued use of the safety syringe.

1. Once administration is complete, return the shroud to an upright position. Disconnect the tube from the shroud by removing the quick connector from atop the shroud.
2. Any remaining product will remain suspended in the connective tube but should be administered immediately.
3. Remove the needle guard. Use the needle removal tool for safety needle removal. Rotate counterclockwise and dispose of the needle into a sharps container.
4. The tubing and safety syringe must be cleaned and lubricated for safe and proper use in the future. Failure to do so may leave the device inoperable. Refer to the safety syringe packaging insert for cleaning instructions.



ADMINISTRATION REMINDERS

- Properly restrain animals prior to administering Micotil.
- With a single hand on the syringe, insert the needle subcutaneously, at a top-down angle, while avoiding penetration of underlying muscle.
- Injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulders and over the ribs.
- Administer a single subcutaneous dose of 1.5 mL to 3 mL of Micotil per 100 lbs.. of body weight.
- Ensure proper disposal of needles, syringes and used bottles.
- If syringe is broken or damaged in any way, discontinue use immediately.
- Exercise caution and care when removing needle from syringe.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

MICOTIL DOSAGE CHART

ANIMAL WEIGHT (LBS.)	MICOTIL DOSAGE		
	1.5 ML/100 LBS. BODY WEIGHT	2.25 ML/100 LBS. BODY WEIGHT	3 ML/100 LBS. BODY WEIGHT
200	3.00	4.50	6.00
300	4.50	6.75	9.00
400	6.00	9.00	12.00
500	7.50	11.25	15.00
600	9.00	13.50	18.00
700	10.50	15.75	21.00
800	12.00	18.00	24.00
900	13.50	20.25	27.00
1,000	15.00	22.50	30.00

HANDLING BEST PRACTICES

- Store Micotil in a lockable cabinet, container or a secure storage room to prevent the risk of misuse is recommended.
  - Recommended storage includes a lockable cabinet or container or a secure storage room, depending on the amount of product in inventory.
- Keep full or empty Micotil bottles, used syringes and needles out of the reach of children and the general public.
- Read, understand and follow all label use directions.
- Micotil must be used with the quick-fit connector made specifically for its use. Contact Elanco or your distributor for this equipment.
- For subcutaneous use. Do not use in automatically powered syringes.
- Use a 1/2˝ to 5/8˝ 18- to 16-gauge needle.
- Keep a protective cover on needles until ready to use.
- Never carry loaded syringes in pocket or clothing.
- Wash hands thoroughly with soap and water after handling.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

WHAT TO DO IN CASE OF SELF-INJECTION

Seek immediate medical attention and:

REACH

for and apply ice pack

REFERENCE

product label and provide to emergency medical personnel

REMEMBER

to call SafetyCall at **800-722-0987** or Elanco at **800-428-4441**

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, 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. 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 lambs less than 15 kg body weight. 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; in sheep: dyspnea and death. Micotil has a pre-slaughter withdrawal time of 42 days.

FULL PRESCRIPTION INFORMATION FOR USE IN CATTLE ONLY. SEE PRODUCT INSERT FOR COMPLETE DOSING AND ADMINISRATION INFORMATION.

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. 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.

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

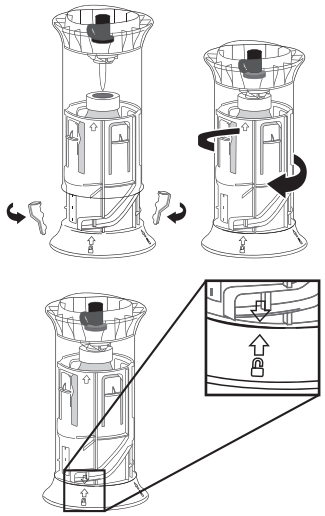
Revised: 09/2021

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.

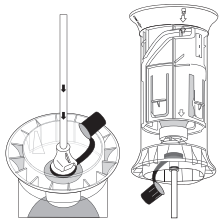
Step 2.
Rotate the Shroud Top through a quarter-turn clockwise. The spike will pierce the vial closure, and the Shroud Top will lock into its final position by an audible "click".

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

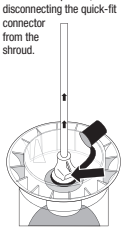


Step 4.
Remove the flexible cap from the fluid connection. Attach the quick-fit connector to tubing if not already attached. Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

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.

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.