



# Micotil<sup>®</sup> 300 (tilmicosin injection)

## Safety Course

Right for cattle. Right by you.

**Elanco**<sup>™</sup>

PM-US-23-0846(3)

# Micotil®300

(tilmicosin injection)

## Safety Course

# Course Format and Learning Objectives

Welcome to the Micotil® Safety Course. Micotil® is an effective and game-changing tool to have in your tool kit against BRD—however, like any injectable, safety is the number one priority. Micotil should only be handled after the completion of the Micotil Safety Course to ensure the lowest risk possible of self-injection.

The Micotil® Safety Course is a four-module educational course:

- Module 1: Micotil® Overview and User Expectations
  - Micotil® Label Indications
  - Micotil® Boxed Warning
  - Micotil® User Expectations
- Module 2: Important Safety Information
  - Micotil® SAFE Principles
  - Micotil® Accidental Human Exposure
- Module 3: Safe Handling and Administration
  - Administration Recommendations
  - Usage Guidelines
  - Micotil® Shroud and Sekurus™ Safety Injector
  - Administration Technique
  - Micotil® How to Shroud Video
- Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning
  - Micotil® Storage Recommendations
  - Micotil® Label Indications
  - Micotil® Boxed Warning

By the end of this four-module educational course, you will be prepared for the responsible use of Micotil®. Once you take the course and complete your certification form submission, your name will be added to our Safe to Sell list and you will be given a certificate of completion which will allow you purchase and administer Micotil®.

**Elanco**<sup>™</sup>

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**Micotil®**  
(tilmicosin injection)

## Safety Course

### **Module 1: Micotil® Overview and User Expectations**

All products have the potential to be misused or used in an unsafe manner. It is important to understand the product label and the user expectations to ensure proper safety and administration for users and animals. This module will explain the:

1. Micotil® Label Indications
2. Micotil® Boxed Warning
3. Micotil® User Expectations

**Elanco**  
TM

# Micotil® 300 (tilmicosin injection) Safety Course

## Module 1: Micotil® Overview and User Expectations



**(tilmicosin injection)**  
300 mg tilmicosin, USP as tilmicosin phosphate per mL

Approved by FDA under NDAs n 140-029

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

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

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

**Additional Information:** For reporting adverse drug experiences for animal drugs, contact FDA at 1-800-FDA-VEIS or http://www.fda.gov/medwatch

**General Pharmacology:** A single subcutaneous injection of Micotil (tilmicosin injection) at 10 mg/kg of body weight dose in cattle resulted in peak tilmicosin levels within one hour and detectable levels (0.07 µg/mL) in serum beyond 3 days. However, lung concentrations of tilmicosin remained above the MIC (MIC 50% of 3.12 µg/g) for *Mannheimia haemolytica* for at least 3 days following the single injection.

**Animal Safety:** A safety study was conducted in feeder calves receiving subcutaneous doses of 20, 30, 40, 60 mg/kg of body weight. Injected 3 times at 72-hour intervals. Deaths were not seen in any of the treatment groups. However, mild hemorrhage at the injection sites were seen in animals at all dosage groups. Lesions were described as being generally more severe and occurred at higher frequency rates in the animals treated with higher dosages (0.200 mg/kg) compared to lower dosages (0.25 mg/kg).

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

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

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

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

**Additional Safety Study:** Under subcutaneous injection, the acute median lethal dose of tilmicosin in mice is 97 mg/kg, and in rats is 185 mg/kg of body weight. In goats, the median lethal dose is 800 mg/kg in mice and 2250 mg/kg body weight in goats and rabbits. Signs, death, deer, cattle, calves, and horses.

**Human Warnings:** Micotil (tilmicosin injection) is not for use in humans. The injection of this medication at any human use is associated with serious, sometimes fatal, allergic reactions. Do not use in lactating dairy cattle 20 months of age or older. Use of tilmicosin in this class of cattle may cause milk residues. Not for use in lactating ewes producing milk for human consumption.

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**Additional Safety Study:** A separate safety study conducted in feeder calves, subcutaneous doses of 10, 30, or 50 mg/kg of body weight injected 3 times at 72-hour intervals did not cause any deaths. Edema at the site of injection was noted.

**Additional Safety Study:** In an additional safety study, subcutaneous doses of 150 mg/kg body weight injected at 72-hour intervals resulted in death of one of the four treated animals.

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**Instructions for Activation of the Shroud**  
Before first usage activate the shroud-injection system as shown in the picture. Activate only with a tube-fed safety syringe. Do not use an automatically powered syringe, single-use syringe, or other delivery device. 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 attach a tube-fed safety syringe and quick-fit connector, contact Elanco at 1-800-428-4441, or your distributor.

**Step 1:** Remove the two lumen-ends of the Micotil Shroud, then prime the tube-fed safety syringe (shown).

**Step 2:** Push the Micotil Shroud through a quarter-bar dockhole. The spike will pierce the seal around the Shroud Top will lock into its final position in a "stable" "click".

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

**Step 4:** 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.

**Step 5:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 6:** 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.

**Step 7:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 8:** 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.

**Step 9:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 10:** 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.

**Step 11:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 12:** 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.

**Step 13:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 14:** 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.

**Step 15:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 16:** 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.

**Step 17:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 18:** 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.

**Step 19:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 20:** 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.

**Step 21:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 22:** 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.

**Step 23:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 24:** 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.

**Step 25:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 26:** 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.

**Step 27:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**Step 28:** 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.

**Step 29:** Remove the Micotil Shroud, then prime the tube-fed safety syringe (shown). Push the quick-fit connector downwards onto the shroud fitting until it clicks into place.

**For cattle and sheep, injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulders and over the ribs.**

**In cattle, administer a single subcutaneous dose of 1.5 to 3.0 mL of Micotil (tilmicosin injection) per 100 lbs of body weight. In other of the two areas noted in the adjacent drawing.**

**For feed cattle, feed quality Assurance recommends injection only if access to the 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. Do not administer with the local intramuscular injection will cause a local reaction, which may result in loss of edible tissue at injection site.**

**Do not use more than 10 mL per injection site.**

**Always follow the manufacturer's instruction of how to safely remove and change needles from the safety syringe.**

**Never use a needle in an appropriate sharps disposal container. Do not overfill sharps containers and do not put your fingers into a sharps container.**

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## Micotil® 300 (tilmicosin injection) Label Indications

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

Right for cattle. Right by you.



PM-US-23-0846(3)

# Micotil® 300 (tilmicosin injection) Safety Course

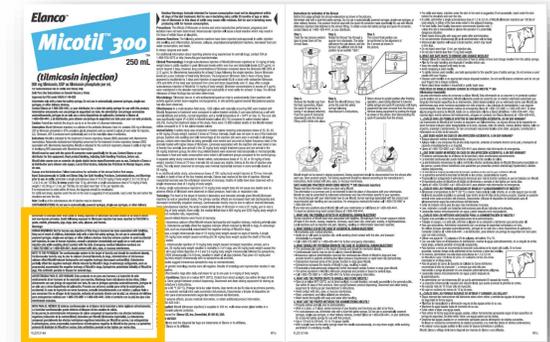
## Module 1: Micotil® Overview and User Expectations

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.**

**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.  $\beta$ -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.**



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**Elanco**

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# Micotil® (tilmicosin injection) Safety Course

## Module 1: Micotil® Overview and User Expectations

### Expectations of ALL Micotil® Users

- Become certified to purchase and administer Micotil®
- Take time to read the full product label and packaging
- Display chute-side poster in all treatment facilities
- Communicate regularly with staff to reinforce good safety practices when working with animals
- Review Micotil® Safe Handling & Use annually with all staff
- Train all new staff prior to allowing the use of any injectable product, including Micotil®
- Follow Proper Drug Use Principles
  - Read, understand and follow all label use directions; in particular, observe all caution statements and human warnings
  - Consult with your veterinarian to determine which product is most appropriate for your situation
- Store Micotil® in a secure location

**MICOTIL® (TILMICOSIN INJECTION) DOSE AND ADMINISTRATION**

**SAFE**

**MICOTIL DOSAGE CHART**

Animal weight (lbs.)	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

**PROPER MICOTIL HANDLING PROCEDURES**

- Store Micotil in a secure location to prevent the risk of misuse.
- 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.
- For subcutaneous use, Do not use in automatically powered syringes.
- Use a 1/2" to 5/8" 18- or 19-gauge needle.
- Keep a protective cover on needles until ready to use.
- Never carry loaded syringes in pockets or by hand.
- Wash hands thoroughly with soap and water after handling.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

**PROPER MICOTIL ADMINISTRATION PROCEDURES**

- Properly restrain animal prior to administering Micotil.
- With a single hand on the syringe, insert the needle subcutaneously at a 45-degree angle with avoiding penetration of underlying muscle.
- Administer a single subcutaneous dose of 1.5 to 3 mL of Micotil per 100 lbs. of body weight in the area noted in the illustration.
- 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 needles from syringe.

**WHAT TO DO IN CASE OF SELF-INJECTION**  
Seek immediate medical attention and:

- REACH** for and apply the patch
- REFERENCE** product label and provide to veterinary medical personnel
- REMEMBER** the name of Micotil or 800-752-4667 or Elanco at 800-426-4411

**IMPORTANT MICOTIL 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. Avoid all contact of needles, syringes, or other delivery devices. Elanco enters cautions to avoid accidental self-injection. In case of human injection, consult a physician immediately and report to an FDA MedWatch representative who providing detailed contact with the area. Avoid contact with eyes.

Always use proper drug handling procedures to avoid accidental self-injection. Consult your veterinarian for 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 associated with fatal and non-fatal reactions, and may be fatal in horses and goats. Do not use in horses, goats or sheep 20 months of age or older. Use in immature dairy cattle or sheep may cause the animals to abort. The following adverse reactions have been reported in cattle: injection site swelling and induration, pyrexia, colic, diarrhea, respiratory distress, and death. Horses have a proconvulsant withdrawal time of 60 days.

**Micotil 300 (Tilmicosin Injection) 250 mL**

**Right for cattle. Right by you. Elanco**

Chute Side Poster

Right for cattle. Right by you. **Elanco**

# Micotil® (tilmicosin injection) Safety Course

## Module 1: Micotil® Overview and User Expectations

### Expectations of ALL Micotil® Users

Take time to read the Client Dispensing Information

- Easy to read and understand format
- Contains:
  - Proper Micotil® Administration Procedures
  - Protective Shroud and Safety Syringe
  - Proper Handling Procedures
  - Important Safety Information
  - What to do in case of accidental self-injection
  - Who to call if you have questions

**Elanco**  
**Micotil**  
Tilmicosin Injection

**MICOTIL® (TILMICOSIN INJECTION)**  
CLIENT DISPENSING INFORMATION

Micotil is indicated for treatment of 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*.

**PROPER MICOTIL ADMINISTRATION PROCEDURES**

- 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.
- Administer a single subcutaneous dose of 1.5 to 3 mL of Micotil per 100 lbs. of body weight in the area.
- 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.

**PROTECTIVE SHROUD AND SAFETY SYRINGE**

Micotil is supplied with a protective, ergonomic case called a shroud and a safety syringe. For your safety, the shroud cannot be removed. Micotil should only be administered with the provided tube-fed safety syringe. This safety syringe leverages self-venting and needle-guard features. The syringe reduces the chance of accidental self-injection and withstands the most challenging environments. Reference the product administration guide for detailed instructions when working with the shroud and safety syringe.

**PROPER HANDLING PROCEDURES**

- 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 19-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 if Elanco at 800-428-4441

Operation name \_\_\_\_\_ Signed Producer \_\_\_\_\_  
Operation address \_\_\_\_\_ Date \_\_\_\_\_  
Operation city, state and ZIP \_\_\_\_\_  
Number of animals \_\_\_\_\_ Location \_\_\_\_\_ Signed Doctor \_\_\_\_\_  
Comments \_\_\_\_\_ Date \_\_\_\_\_

white copy: producer | yellow copy: veterinarian

**SAFE**  
SAFETY AND PROTECTIVE EQUIPMENT

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### Client Dispensing Information

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PM-US-23-0846(3)

# Micotil® (tilmicosin injection) Safety Course

## Module 1: Micotil® Overview and User Expectations

### Expectations of Veterinarians

- Veterinarians should be trained and recertified by Elanco representatives or complete the online training modules.
- Veterinarians should discuss Micotil® safe handling and use with their clients and work with clients to define a proper, secure storage location prior to dispensing.
- Dispense Micotil® when a valid Veterinarian-Client-Patient Relationship (VCPR) is in place.
- Veterinarians should develop their own procedure to document (i.e., Safe to Sell list) which clients have been trained.

### Expectations of Suppliers

- Suppliers should be trained and recertified by Elanco representatives or complete the online training modules
- Suppliers should discuss Micotil® safe handling and use with their clients before dispensing Micotil®.
- Suppliers should develop their own procedure to document (i.e., Safe to Sell list) which clients have been trained.
- Upon receipt of Micotil® orders, suppliers should check their Safe to Sell list to ensure accounts are active before dispensing

**Micotil® (TILMICOSIN INJECTION)**  
DOSE AND ADMINISTRATION

**SAFE**

**Micotil DOSAGE CHART**

Animal weight (lbs.)	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

**PROPER MICOTIL HANDLING PROCEDURES**

- Store Micotil in a secure location to prevent the risk of misuse.
  - 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.
- For subcutaneous use. Do not use in automatically powered syringes.
- Use a 1/2" to 5/8" 18- or 19-gauge needle.
- Keep a protective cover on needles until ready to use.
- Never carry loaded syringes in pockets or by hand.
- Wash hands thoroughly with soap and water after handling.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

**PROPER MICOTIL ADMINISTRATION PROCEDURES**

- Properly restrain animal prior to administering Micotil.
- With a single hand on the syringe, insert the needle subcutaneously at a 45-degree angle with avoiding penetration of underlying muscle.
- Administer a single subcutaneous dose of 1.5 to 3 mL of Micotil per 100 lbs. of body weight in the area noted in the illustration.
- 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 needles from syringe.

**WHAT TO DO IN CASE OF SELF-INJECTION**  
Seek immediate medical attention and:

- REACH** for and apply the patch
- REFERENCE** product label and provide to veterinary medical personnel
- REMEMBER** the name of Micotil or 800-725-4667 or Elanco at 800-426-4411

**IMPORTANT MICOTIL 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. Avoid use of needles, syringes, or other delivery devices. Exercise extreme caution to avoid needle self-injection. In case of human injection, contact a physician immediately and report to or call the manufacturer who promptly should contact with the state health department.

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 associated with fatal and non-fatal reactions, possibly, and may be fatal in horses and goats. Do not use in horses, dairy cattle 30 months of age or older that is milating dairy cattle or whose milk may be used for human consumption. The following animals have been reported to react: lactating dairy cattle, sheep, goats, horses, and goats. Injection also causing and exacerbating, respiratory, colic, and/or diarrheal reactions, and death. Microbial safety procedures: withdrawal time of 42 days.

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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 1: Micotil<sup>®</sup> Overview and User Expectations

As you can see, a proper understanding of the label indications and user expectations reduces the potential for products to be misused or used in an unsafe manner.

Our next module will go on to cover an overview of Important Safety Information for Micotil<sup>®</sup>.

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PM-US-23-0846(3)

**Micotil<sup>®</sup>**  
(tilmicosin injection)

## Safety Course

### Module 2: Important Safety Information Overview

Safety is imperative when handling any injectable product, including Micotil<sup>®</sup>. This module will explain the:

1. Micotil<sup>®</sup> SAFE Principles
2. Micotil<sup>®</sup> Accidental Human Exposure

**Elanco**<sup>™</sup>

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### *Safe Use Principles*

Principle 1: **S**afety for you (caregiver)

Principle 2: **A**nimal Safety

Principle 3: **F**ood Chain Safety

Principle 4: **E**nvironmental Safety



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 1 Safety for you (caregiver)

#### *Exercise Caution to Avoid Accidental Self-injection*

- Keep children and bystanders out of work area
- Properly restrain all animals
- Be aware of uneven or changing walking surfaces
- NEVER work alone – always work in a team
- Clearly establish a team leader and roles
- Evaluate the experience of those around you
- Identify an exit route



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 1 Safety for you (caregiver)

#### Syringe and Needle Precautions

- Keep needles properly covered until use
- Exercise caution and care when removing needle from syringe to not pierce skin with needle
- **ALWAYS** use safety syringe with quick connect draw off tubing
  - Elanco **ONLY** recommends use of the Sekurus<sup>™</sup> Safety Injector, which features a two-stage activation process to reduce risk of accidental injection
  - Do not use in automatically powered syringes (hydraulic, CO2 or needleless) where delivery of injection cannot be controlled
  - Do not use non-safety self refilling syringes or disposable syringes
  - Handle loaded syringes with care
  - Carry syringe in proper manner to ensure safe handling
  - Only carry loaded syringes in a tote or container; NEVER carry loaded syringes in your clothing
  - If syringe is broken or damaged in any way, discontinue use immediately and replace



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 2 Animal Safety

- Use adequate facilities
  - Squeeze chute
  - Head gate
- Minimize handling stress in accordance with animal behavior
- Adjust your activity to the temperament of each animal
- If an animal cannot be properly restrained or there is concern about operator skill, consider using alternative treatments



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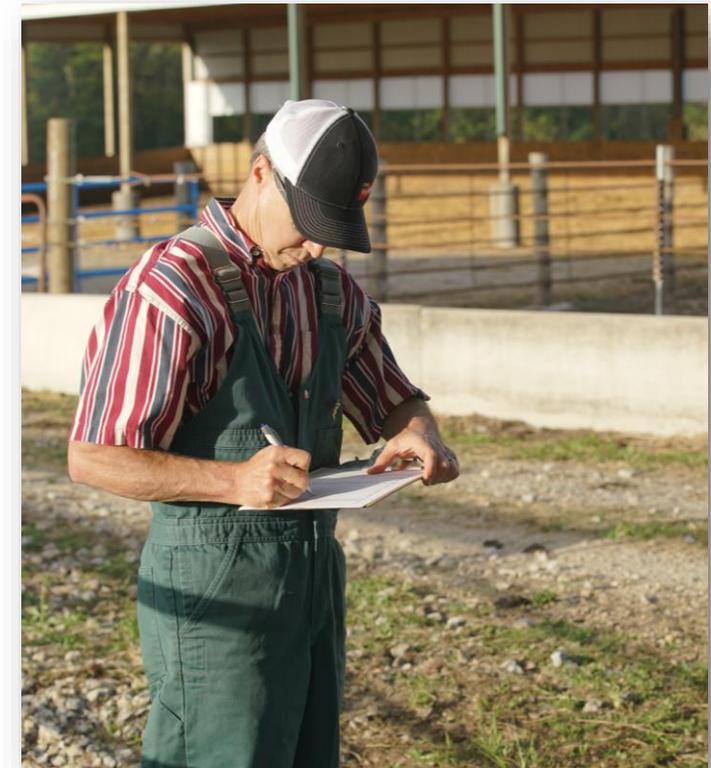
PM-US-23-0846(3)

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 3 Food Chain Safety

- Use only FDA-approved products
- Strictly observe label directions
  - Dose, route, cautions, warnings, withdrawal times, etc.
- Record all products administered
  - ✓ Animal ID
  - ✓ Date treated
  - ✓ Product used
  - ✓ Dosage
  - ✓ Route and location of administration
  - ✓ First marketing date to meet withdrawal requirements (Pre-slaughter withdrawal time for Micotil is 42 days)



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# Micotil® (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 4 Environmental Safety

- Post-emergency procedures and contacts  
Call:  
- **SafetyCall International at 1-800-722-0987 or**  
- **Elanco Animal Health at 1-800-428-4441**
- Remove potential hazards in work area
- Repair or remove broken equipment
- Properly dispose of used needles and bottles
- Recycle all injectable syringes and bottle packaging

**MICOTIL® (TILMICOSIN INJECTION)**  
DOSE AND ADMINISTRATION

**MICOTIL DOSAGE CHART**

Animal weight (lbs.)	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

**PROPER MICOTIL HANDLING PROCEDURES**

- Store Micotil in a secure location to prevent the risk of misuse.
- 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.
- For subcutaneous use, Do not use in automatically powered syringes.
- Use a 1"0" to 3"10" 18- or 20-gauge needle.
- Keep a protective cover on needles until ready to use.
- Never carry loaded syringes in pockets or by hand.
- Wash hands thoroughly with soap and water after handling.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

**PROPER MICOTIL ADMINISTRATION PROCEDURES**

- Properly restrain animal 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.
- Administer a single subcutaneous dose of 1.5 to 3 mL of Micotil per 100 lbs. of body weight in the area noted in the instruction.
- 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 needles from syringe.

**WHAT TO DO IN CASE OF SELF-INJECTION**  
Seek immediate medical attention and:

- REACH** for and apply eye patch
- REFERENCE** product label and provide to emergency medical personnel
- REMEMBER** to call SafetyCall at 800-722-0987 or Elanco at 800-428-4441

**IMPORTANT MICOTIL 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.** Injections of this drug in humans has been associated with fatalities. Keep out of reach of children. Administer only with a licensed family 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 ingestion, contact a physician immediately and apply for or seek poison information advice. Avoid contact with eyes. Avoid contact with body. Avoid contact with body. Avoid contact with body. Avoid contact with body.

**Warnings:** See product insert for detailed information on safety and efficacy. Consult your veterinarian on the safe handling and use of all injectable products prior to administration. For use in cattle or horses only, right subcutaneous injection of this drug has not been shown to be safe in water and non-ruminant species, and may be fatal in horses and goats. Do not use in horses other than 20 months of age or older. Use in horses other than 20 months of age or older may cause milk residues. The following adverse reactions have been reported in cattle: reaction site swelling and inflammation, tremors, colic, anisocoria, myasthenic weakness, decreased food and water consumption, and death. Micotil has a pre-withdrawal withdrawal time of 90 days.

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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

### Safe Use Principles: Principle 4 Environmental Safety

#### Possible Effects of Accidental Human Injection

- Human injections of Micotil have been associated with fatalities
- Clinical signs of 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

#### Human-Exposure Actions

- If accidental exposure occurs seek immediate medical attention:
  - REACH for and apply ice pack
  - REFERENCE product label “Note To The Physician” and/or product insert and provide to doctor
- REMEMBER to contact SafetyCall at 1-800-722-0987 or Elanco Animal Health at 1-800-428-4441 (select product support)

### 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

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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 2: Important Safety Information Overview

As you can see, safety precautions must be taken across all fronts. This ensures that all parties are kept healthy and safe.

Our next module will go on to cover the Safe Handling and Administration of Micotil<sup>®</sup>.

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PM-US-23-0846(3)

**Micotil<sup>®</sup>**  
(tilmicosin injection)

## Safety Course

### Module 3: Safe Handling and Administration

This module will cover the handling and administering of Micotil<sup>®</sup> to ensure the best safety protocols are taken. When administration recommendations are taken into account, this allows for a reduced risk of injury to both the animal and the human.

This module will explain:

1. Administration Recommendations
2. Usage Guidelines
3. Micotil Shroud and Sekurus Syringe
4. Administration Technique
5. Micotil<sup>®</sup> How to Shroud Video

**Elanco**<sup>™</sup>

PM-US-23-0846(3)

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Administration Recommendations

- Always keep needles properly covered until ready to use
- Carry syringe in proper manner to ensure safe handling
- Handle loaded syringes with care
- Never carry loaded syringes in coat or pockets
- If syringe is broken or damaged in any way, discontinue use immediately and replace
- Exercise caution and care when removing needle from syringe so as not to pierce skin with needle
- Elanco recommends that Micotil<sup>®</sup> be administered only by those individuals who have received safe handling and use training from their veterinarian or an Elanco representative
- Producers should consider designating one trained and responsible individual on their animal health team to administer Micotil<sup>®</sup>
- It is recommended that Micotil<sup>®</sup> only be used in situations where animals can be properly restrained
  - Producers should consult their veterinarian for specific restraint recommendations
- Generally, proper animal restraint would include restraint via a squeeze chute, head gate, headlock or similar device



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PM-US-23-0846(3)

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Usage Guidelines

- Administer only with a tube-fed safety syringes. Do not use in automatically powered syringes, single-use syringes, or other delivery devices not specified in the labeling.
- Inject subcutaneously in cattle and sheep only. Do not administer intravenously; intravenous injection will be fatal
  - In cattle, administer a single subcutaneous dose of 10 to 20 mg/kg of body weight (1.5 to 3 mL/100 lbs). Do not use in female dairy cattle 20 months of age or older. Use of tilmicosin in this class of cattle may cause milk residues. Do not use in lactating ewes if the milk is intended for human consumption.
  - In sheep greater than 15 kg (30 lb), administer a single subcutaneous dose of 10 mg/kg of body weight (1.5 mL/100 lbs). Do not use in lambs less than 15kg (30lb) body weight.
  - Do not inject more than 10 mL per injection site
- Animals intended for human consumption must not be slaughtered within 42 days of the last treatment
- If no improvement is noted within 48 hours, the diagnosis should be re-evaluated.
- 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.
- Effects of tilmicosin on bovine and ovine reproduction, pregnancy and lactation have not been determined

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PM-US-23-0846(3)

# Micotil® (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Micotil® Bottle Shroud and Sekurus™ Safety Injector

- Micotil® is supplied with a protective, ergonomic case called a shroud. For your safety, the shroud cannot be removed.
- The shroud must be activated and connected to the appropriate quick connect draw-off tubing prior to use.
- The shroud offers added protection from breakage during the handling of bottles.
- Micotil® should only be administered with the Sekurus™ Safety Injector.
  - To obtain a Sekurus™ Safety Injector for the administration of Micotil®, please contact your Elanco Sales Representative or call 1-800-428-4441.



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PM-US-23-0846(3)

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Micotil<sup>®</sup> Bottle Shroud

- All product information contained in accordion style label on Micotil<sup>®</sup> packaging
- Easy to read & understand format
- Discusses safety to the worker
- Contains:
  - Important safety information
  - Shroud activation instructions
  - What to do in case of accidental self-injection
  - Who to call if you have questions



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Micotil<sup>®</sup> Bottle Shroud- Use Instructions

1. Gather materials to administer Micotil<sup>®</sup>. 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. Micotil<sup>®</sup> should only be administered with the quick-fit connector made specifically for its use along with the tube-fed safety syringe.
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.

**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.

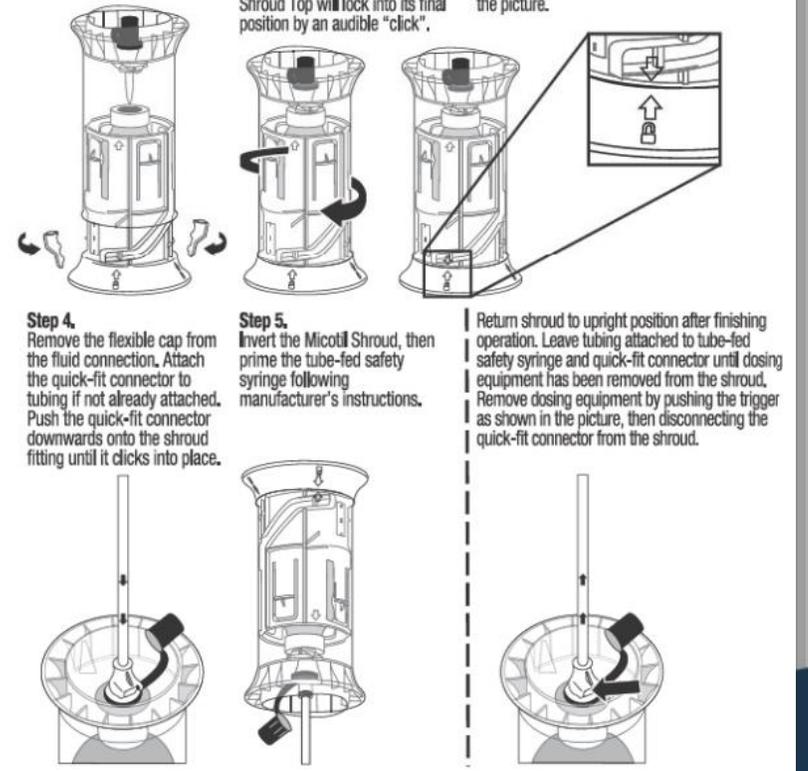
**Step 2.** Rotate the Shroud Top through a quarter-turn clockwise. The spike will pierce the vial closure, and the Shroud Top will lock into its final position by an audible "click".

**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.



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# Micotil® (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Sekurus™ Safety Injector

- Elanco recommends use of the Sekurus™ Safety Injector, which features a 2-stage activation process to reduce risk of accidental injection
- Patented self-tenting technology
  - Makes sure operator's hand is not close to injection site
- Two-stage activation
  - To activate, pull the trigger & then push the syringe cone against the animal
  - Both must be performed in order to expose the needle & insert it into the animal
  - Depress the syringe handle to inject Micotil® into the animal



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Sekurus<sup>™</sup> Safety Injector- Use Instructions

- Prime the safety syringe
- Set the dose adjuster to the maximum setting.
- Grasp the safety syringe and depress the trigger with the forefinger
- Using your spare hand, pull the needle guard back and hold in this retracted position for the remainder of the priming procedure.
- 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.
- Allow the needle guard to return forward and release trigger.
- Set the dose adjuster to the required setting.



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Sekurus<sup>™</sup> Safety Injector- Use Instructions cont.

- To attach the needle, 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.
  - Keep your thumb and fingers on the metal slide so they are well clear of the trigger.
  - Remove the cap from the needle cover (do not remove the cover from the needle until it is attached to the syringe.)
  - Use the needle cover to properly fit the appropriately sized needle (proper needle length should be ½" to 5/8") onto the tip and rotate clockwise to engage threads. Avoid over tightening the needle.
  - To remove the needle, place the needle cover over the needle and twist in the opposite direction (counterclockwise)
  - If needle cannot be removed using needle cover, use needle-nosed pliers to remove. Never remove by hand.
  - 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.



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# Micotil® (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Sekurus™ Safety Injector- Use Instructions cont.

- Injecting with the gun
  - Place the cone of the syringe onto the neck area at a downward angle
  - Simultaneously push cone of the syringe into neck while depressing the syringe trigger to expose the needle & penetrate the skin
  - Once the needle has penetrated the skin, shift the hand with syringe toward the animal, pulling the skin away from the deeper muscle tissue
  - Depress the handle to complete the injection
- **Remember**
  - DO NOT use the opposite hand to tent the skin
  - Use only one hand (the other hand should be kept away from the injection area)
  - Ensure proper disposal of needles, syringes and used bottles
  - Discuss any concerns with your veterinarian



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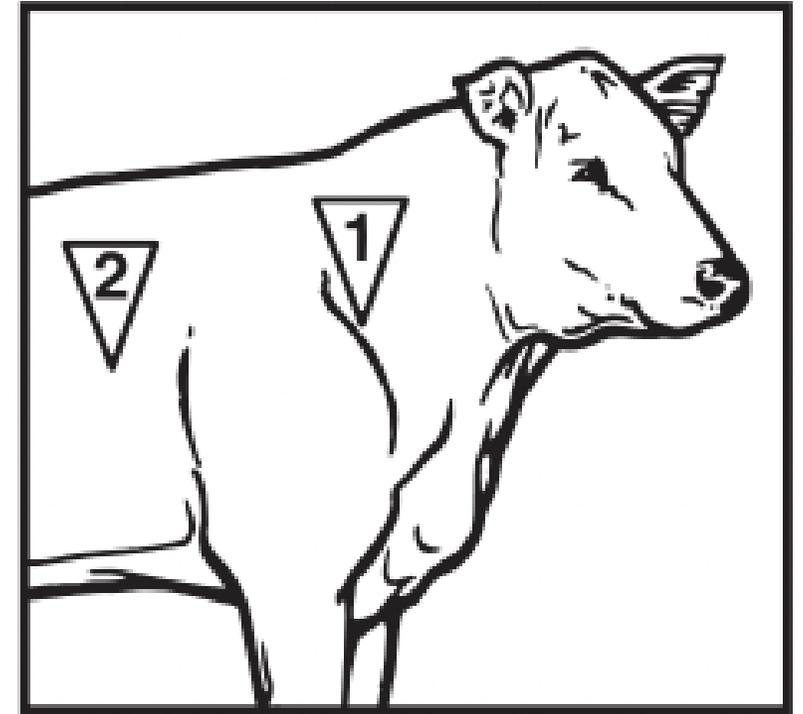
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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Administration Technique

- Select a 1/2" to 5/8", 18- to 16- gauge needle
- 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 10 to 20 mg/kg of body weight (1 to 2 mL/30 kg or 1.5 to 3 mL per 100 lbs)



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling and Administration

### Micotil<sup>®</sup> How to Shroud Video

For a video demonstration of how to use the Micotil<sup>®</sup> Bottle Shroud and Sekurus Device please visit the link below or click play on the video embedded in this slide.

<https://www.youtube.com/watch?v=jbKsKgCsl44>



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**Elanco**<sup>™</sup>

PM-US-23-0846(3)

# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 3: Safe Handling & Administration

By adhering to these usage and administration guidelines, you can be confident in your safe use of Micotil<sup>®</sup> .

Our next module will go on to cover the Micotil<sup>®</sup> Storage Recommendations and a final review of the Micotil<sup>®</sup> Label Indications and Micotil<sup>®</sup> Boxed Warning.

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PM-US-23-0846(3)

**Micotil®**  
(tilmicosin injection)

## Safety Course

### **Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning**

Once you finish using Micotil®, storing it in a safe place is just as important. By doing this, you ensure that only those allowed to administer Micotil® can access it, and that it will stay out of reach of the general public. This module will cover the storage of Micotil® to prevent misuse and perform a final review of the label indications and boxed warning.

1. Micotil® Storage Recommendations
2. Micotil® Label Indications
3. Micotil® Boxed Warning

**Elanco**<sup>TM</sup>

PM-US-23-0846(3)

# Micotil® (tilmicosin injection) Safety Course

## Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning

### Storage Recommendations

- Storage of Micotil® in a secure location to prevent misuse is recommended. The risk of misuse by humans should be considered when storing, administering and disposing of Micotil®.
- Recommended storage method is in a locked cabinet, storage room or a similar secure container, depending on inventory
- Keep full or empty Micotil® bottles, used syringes and needles out of the reach of children and the general public.
- Store at or below 86° (30°C). Protect from direct sunlight. Use within 84 days of first puncture. Store upright between product dispensing. Disconnect and clean dosing equipment for storing as per manufacturer's instructions



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PM-US-23-0846(3)

# Micotil® 300 (tilmicosin injection) Safe Course

## Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning



300 mg tilmicosin, USP as tilmicosin phosphate per mL

See the Instructions for Use and the boxed warning only

See the Instructions for Use and the boxed warning only

Approved by FDA under NADA # 141-023

Administer only with a lube-rod 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 lube-rod safety syringe for use with this product.

Administer intramuscularly on a single injection on the neck, but do not administer on the neck or on the head.

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**Residue Warnings:** Animals intended for human consumption must not be slaughtered within 10 days of the last treatment. Do not use in lactating dairy cattle 30 months of age or older.

**Use of Tilmicosin in this class of cattle may cause milk residues. Milk use in lactating ewes producing milk for human consumption.**

**Precautions:** The effects of tilmicosin on bovine and ovine reproductive performance, pregnancy and lactation have not been determined. Intramuscular injection will cause a local reaction which may result in firm areas of edema tissue at the injection site.

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

**Precautions:** In sheep, dyspnea and death.

**Additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch**

**Clinical Pharmacology:** A single subcutaneous injection of Micotil (tilmicosin) injected at 10 mg/kg of body weight in cattle resulted in peak tilmicosin levels within one hour and detectable levels (0.27 µg/mL) in serum beyond 5 days post-injection at approximately 60 days. In a study with radioactive tilmicosin, 24% and 66% of the dose was recovered from urine and feces respectively over 21 days. After a single subcutaneous injection of Micotil at 10 mg/kg body weight, tilmicosin was detected in excreta of a piglet, were maintained in the alveolar macrophages and neutrophils of most cattle for at least 10 days. The clinical significance of these findings has not been determined.

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

**Effectiveness:** In a multi-location field study, 1508 calves with naturally occurring BRD were treated with Micotil. Responses to treatment were compared to saline-treated controls. A cure was defined as a calf with normal appetite and activity, normal respiration, and a rectal temperature of <104°F on Day 13. The cure rate was significantly higher (P<0.001) in Micotil-treated calves (83.1%) compared to saline-treated calves (22.2%). During the treatment phase of the study, there were 10 BRD-related deaths in the Micotil-treated calves compared to 17 in the saline-treated calves.

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

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

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

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

**Toxicology:** The heart is the target of toxicity in laboratory and domestic animals given Micotil (tilmicosin) injection orally or parenterally routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractile (negative inotropic) properties. Cardiac toxicity may be due to calcium channel blockade. Upon subcutaneous injection, the acute median lethal dose of tilmicosin in mice is 87 mg/kg, and in rats is 185 mg/kg of body weight. Given orally, the median lethal dose is 800 mg/kg and 2200 mg/kg body weight in fasted and nonfasted rats, respectively.

No compound-related lesions were found at necropsy.

In sheep, intramuscular injection of 10 mg/kg body weight caused increased respiration, emesis, and a convulsion. 20 mg/kg body weight resulted in mortality in 3 of 4 pigs, and 30 mg/kg body weight caused the death of 4 of 4 piglets. Mortality occurred at 4.5 mg/kg body weight followed by convulsions. In rats, (1-1000) intravenously 2 to 6 times, resulted in death of all pigs injected. Pigs given 4.5 mg/kg and 15.0 mg/kg body weight intravenously with no respiratory or other signs of toxicity.

These results suggest intramuscular epinephrine may be cardioprotective.

Results of genetic toxicology studies were all negative. Results of teratology and reproduction studies in rats were negative.

The no effect level in dogs after daily oral doses for up to one year is 4 mg/kg of body weight.

**Storage Conditions:** Store at or below 86°F (30°C). Protect from direct sunlight. Use within 84 days of first puncture. Store single-use syringes in original container. Discard any unused syringes for storage as per manufacturer's instructions.

Conserve at 86°F (30°C). Protect from the heat and light. Use within 84 days of the first puncture. Discard any portion used after 84 days of first puncture. Store single-use syringes in original container. Discard any unused syringes for storage as per manufacturer's instructions.

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**Instructions for Activation of the Shroud:** Do not lift using the shroud or the activation button as shown in the pictures.

**Use of Micotil in this class of cattle may cause milk residues. Milk use in lactating ewes producing milk for human consumption.**

**Precautions:** The effects of tilmicosin on bovine and ovine reproductive performance, pregnancy and lactation have not been determined. Intramuscular injection will cause a local reaction which may result in firm areas of edema tissue at the injection site.

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The no effect level in dogs after daily oral doses for up to one year is 4 mg/kg of body weight.

**Storage Conditions:** Store at or below 86°F (30°C). Protect from direct sunlight. Use within 84 days of first puncture. Store single-use syringes in original container. Discard any unused syringes for storage as per manufacturer's instructions.

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For cattle and sheep, injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulders and over the ribs.

In cattle, administer a single subcutaneous dose of 1.5 to 3.0 mL of Micotil (tilmicosin injection) per 100 lbs of body weight. In other of the two areas noted on the adjacent diagram.

Do not administer intravenously. Do not administer with local anesthetic. Do not use in lactating dairy cattle 30 months of age or older.

For best cattle, best quality livestock, recommend injection site 1" above the site as accessible or places the operator in a potentially dangerous situation.

Wash hands thoroughly with soap and water after administration.

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## Micotil® 300 (tilmicosin injection) Label Indications

- Micotil® is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* and for the treatment of ovine respiratory disease (ORD) associated with *Mannheimia haemolytica*

- Micotil® is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*

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# Micotil® 300 (tilmicosin injection) Safety Course

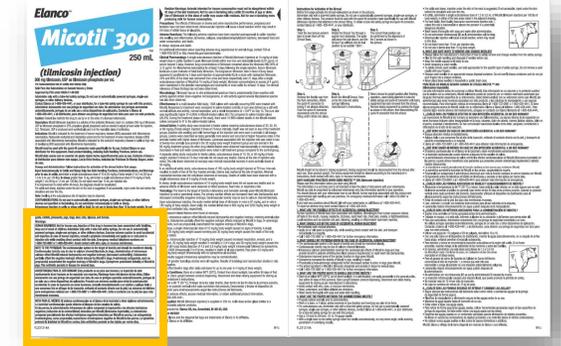
## Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning

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.

**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.  $\beta$ -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.



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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

## Module 4: Micotil<sup>®</sup> Storage Recommendations, Review of Micotil<sup>®</sup> Label Indications and Micotil<sup>®</sup> Boxed Warning

As you can see, storage is just as important as every other step we have discussed today. It is also important to understand the product label to ensure proper safety and administration for users and animals.

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# Micotil<sup>®</sup> (tilmicosin injection) Safety Course

Thank you for completing the Micotil<sup>®</sup> (tilmicosin injection) Safety Course. We hope that this educational course has provided lifelong safety information to you, and that you will follow these protocols while administering Micotil<sup>®</sup> and other injectables for maximum safety.

**Please download the Certification Signature Page from the Micotil Safety Training site, sign, and send completed form to [Micotil\\_Certification@elanco.com](mailto:Micotil_Certification@elanco.com).**

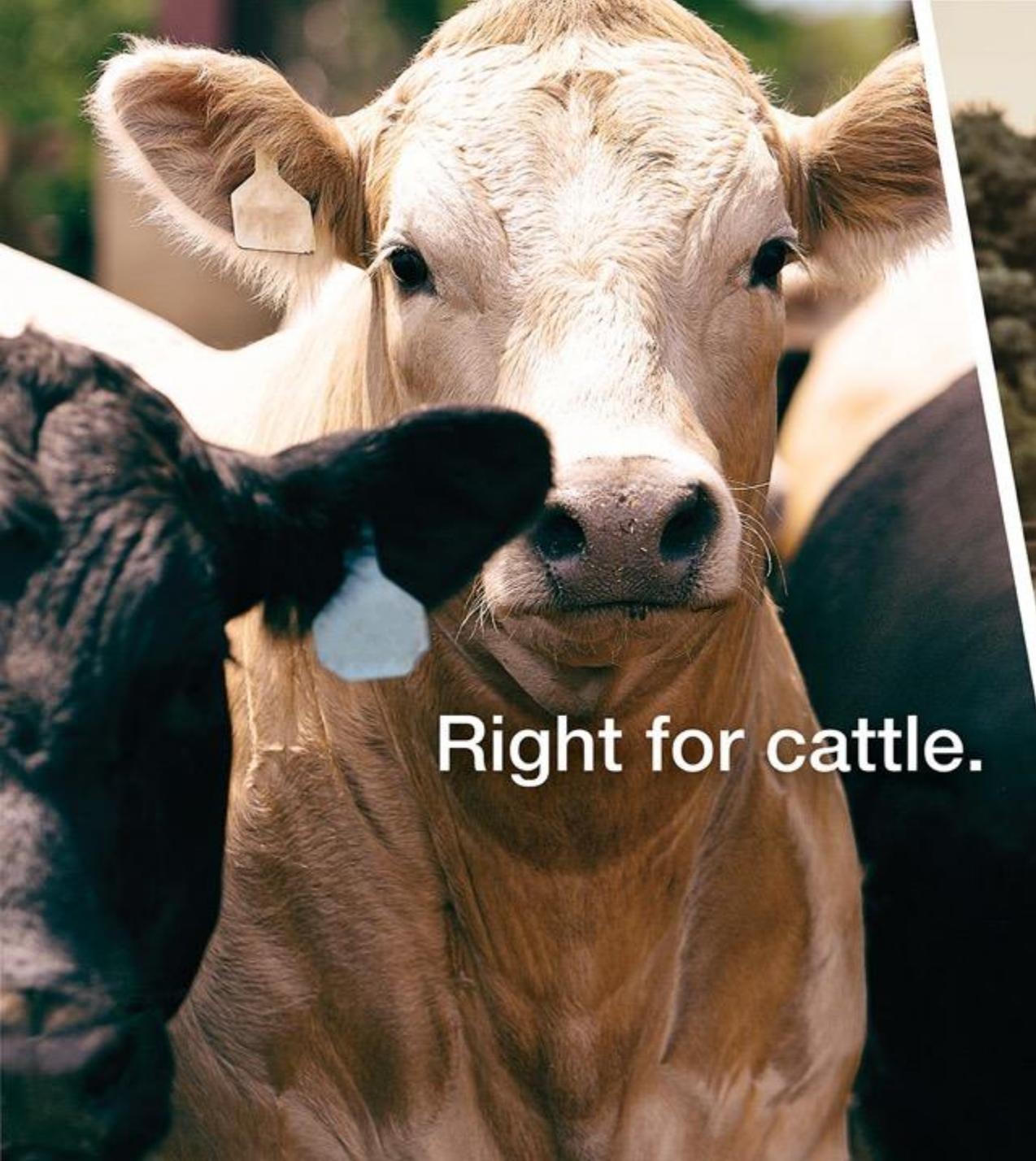
For questions regarding Micotil<sup>®</sup> or this Safety Course, please contact your Elanco Sales Representative or call 800-428-4441.

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Other company and product names are trademarks of their respective owners.  
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