

Micotil® 300

(tilmicosin injection)

Safety Course

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®.

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



Module 1: Micotil® Overview and User Expectations



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Winnings: GRAMM MANINGS for for human use, bijection of the drug in humans has been associated with trialfiles. Keep out of reach of childres, Administer only with a habe-flat soldly grippe, Do not on an instanticity, and the property of the property o

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Residue Warnings, Animas intended for insunan consumption must not be stasighted within 42 days of the last freatment. Not for use in lactating dairy cattle 20 months of age or older. Use of tilinicosin in this dass of cattle may cause milk residues. Not for use in lactating ewes producing milk for human consumption.

Precaudions: The effects of tilinicosin on bovine and ovine reproductive performance, pregnancy and Adverse Reactions: The following adverse reactions have been reported post-approval: In cattle: injection For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.tda.gov/reportanimalae 1-864-F0-VETS of thy (invention, age) report animals.

Clinical Pharmacelogists A stripp and content of the content of the content in the content of the con subcutaneous injection of Micotil at 10 mg/kg of body weight, tilmicosin concentrations in excess of 4 µg/mi were maintained in the alwoolar macrophages and neutrophils of most cattile for at least 10 days. The clinical relevance of these findings has not been determined. Microbiology: Talmicosin has an in witro antibacterial spectrum that is predominantly Gram-positive with activity against certain Gram-negative microorganisms, in witro activity against several Mycoplasma spei has also been observed.

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Significantly higher Feedloop in Model-Headed deedle Sich 31°s compared to a similar-branded celebrate of the study. Here were 10 SEO-related deaths in the Model-Person of Compared to 4°I his similar-branded celebrate.

Animal Safety: A safety study was conducted in feeder calves receiving subcutaneous doses of 20, 30, 40, or 60 mg/kg of body weight, injected 3 times at 72-hour intervals. Death was not seen in any of the treatment groups. Injection site swelling and milld hemorrhage at the injection site were seen in animals in all dosage groups. Lesions were described as being generally more severe and occurred at higher frequency rates in the animals treated with higher doses of filmicosis. Lameness associated with the injection site was noted in two of twenty-four animals (one animal in the 30 mg/kg body weight treatment group and one animal in the 80 mg/kg treatment group). No other dury elated lesions were observed mancroapposally or increapposal 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 does 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 oted. The only lesion observed at necropsy was minimal myocardial necrosis in some animals closed a

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Toxicology: The heart is the target of toxicity in laboratory and domestic animals given Micotil (tilmicosi injection) by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy). Cardiovascular toxicity may be due to calcium channel blockade. Upon subcutaneous injection, the acute median lethal dose of tilmicosin in mice is 97 mg/kg, and in rats is 185 mg/kg of body weight. Given orally, the median lethal dose is 800 mg/kg and 2250 mg/kg body weight in frated and norifasted rats, respectively.

to compound-related lesions were found at necropsy. In does, intravenous calcium offset Micotli-induced factivicardia and negative inotropy, restoring arterial puls issure. Dobutamine partially offset the negative instrucic effects induced by Micotil in doos, 6- adrenergic intagonists, such as programofol, exacerbated the negative ingtropy of Micotil in dogs,

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These means acquire interevolvasity with no expressions and survived. Results of genetic toxicology studies were all negative. Results of teratology and reproduction studies in rats

were negative.

The no effect levell in dogs after daily orall 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 surifigint. Use within 84 days of first puncture. Store upright between product dispensing. Disconnect and dean dosing equipment for storing as per ground-storing in principles.

How Supplied: Micotil (tilmicosin injection) is supplied in 250 ml. multi-dose amber glass bottles in a

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

Micotil, Blanco and the diagonal bar logo are trademarks of Elanco or its affiliates. © 2022 Flanco or its affiliates

instructions for Administrate of the Serviced Before first stage activities the shrows-delepation as shown in the pictures. Administration only with a bit-field safety springe, Don of use in automatically powered springes, single-use springes, or other delevely elevants. This product must be used with the quise! Fromorator must specifically for use with Microll (direction injection) that database to the shrowed filting. To obtain a bits-field safety springe and quick-fit connector, control fallows of 2-40-244-4441, or pre-delebitury. Stage 1, the largest evident stage is the Strout Fig through a flow of the Strout Fig th



Microfil should not be stored in dosing equipment, Dosing equipment should be disconnected from the shroud after SAFE HANDLING PRACTICES WHEN USING MICOTIL™ 300 (tilmicosin injection)

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1-800-428-441, Flyon have any questions about Micrall, talk with your veterinaries or call Banco at 1-800-429-4441, for root an adverse drug went contact libero at 1-800-429-4441. JMEA JOER TO ASSOCIATE STREETS of ENCORPORT MICROSORIES MICROSORIES OF A STREET MICROSORIES AND A STREET MICRO 2, WHAT SHOULD I DO IN THE CASE OF ACCIDENTAL HUMAN INJECTION?

Immodutery seek menica asternor.
 Apply ice or cold pack to injection site, while avoiding direct contact with the skin, and transport immediately to a hospital.
 Call 1-800-722-9857 or 1-809-428-4441 for further emergency information.

• Call Hout, P.Z. John (*) - House designer; information, and the processing of t

randol (a beta-adrenergic antagonist) further decreased cardiac function in dogs given Micoti active ingredient in Micoti is tilmicosin phosphate and persists in tissue for several days, 11-800-722-0987 or 1-800-428-4441 for further emergency information.

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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. behind the shoulders and over the ribs.

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dangerous situation.

Wash hands thoroughly with soap and water after administration.

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6. WHAT ARE SAFE WAYS TO REMOVE AND CHANGE NEEDLES?

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your fingers into a sharps container, Never place loose needles in household or public trash cans.

filmicosina inyectable) ea esta información antes de comenzar a utilizar Micotil. Esta información es un resumen y no pretende sustituir Las et al mómición entre de converse a sibility Mesil. Esta inheración es un resumen y no priende subtili-cia de la másic con su vietnera. Mosti disenten al use a presentir por unidad ventre a discinada que traya la riferencia de sepectra de las inheración, blade disede a valual con su externación usual Mesil. Assistantes considerantes de la considera de la cons

2. ¿QUÉ DEBO HACER EN CASO DE UNA INYECCIÓN ACCIDENTAL A UN SER HUMANO?

 Busque atención médica inmediatamente.
 Aplique hielo o una compresa fría al sitio de la inyección, evitando el contacto directo con la piel, y transporte al paciente inmediatamente a un hospital. Llame al 1-800-722-0987 o al 1-800-428-4441 para obtener más información de emergencia

3. ¿QUÉ DEIR SARRI MI MÉDICO DE CINA DE LINA INVECCIÓN ACCIDENTAL A UN SER HUMANO?

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4. COULDS SON LOS Frances substitutions on stokes, by 4 Multicolabeletrin to a stoke 1, 1 million of the country of the countr 5. ¿CUÁLES SON LOS MÉTODOS ADECUADOS PARA LA ADMINISTRACIÓN DE MICOTIL?

Sujetar a los animales en forma apropiada antes de la administración. Trabajar en equipo, o si está solo, informar a alguien de su ubicación y del tiempo que piensa estar allí. Para uso subcutáneo. Administrar únicamente con una jeringa de seguridad conectada a un tubo. No utilizar jeringas operadas automáticamente, jeringas de un solu uso utros dispositivos e aplicación. Contactar a Elanco al 1-800-428-4441, o al distributior, para obtener una jeringa de seguridad con tubo

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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

Elanco

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. 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.



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



Chute Side Poster



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



Client Dispensing Information



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



Chute Side Poster



Module 1: Micotil® 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®.

Micotil® (tilmicosin injection)

Safety Course

Module 2: Important Safety Information Overview

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

- 1. Micotil® SAFE Principles
- 2. Micotil® Accidental Human Exposure



Module 2: Important Safety Information Overview

Safe Use Principles

Safety for you (caregiver) Principle 1:

Principle 2: **A**nimal Safety

Food Chain Safety Principle 3:

Environmental Safety Principle 4:



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



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 SekurusTM 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





Module 2: Important Safety Information Overview

Safe Use Principles: Principle 2 Animal Safety

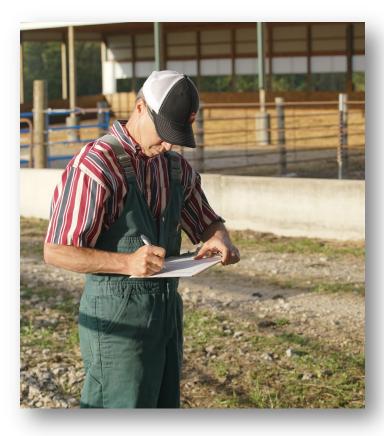
- Use adequate facilities
 - Squeeze chute
 - Head gate
- Minimize handling stress in accordance with animal behavior
- Adjust your activity to the temperament of each animal
- If an animal cannot be properly restrained or there is concern about operator skill, consider using alternative treatments



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 (Preslaughter withdrawal time for Micotil is 42 days)



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



Chute Side Poster



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)



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®.

Micotil® (tilmicosin injection)

Safety Course

Module 3: Safe Handling and Administration

This module will cover the handling and administering of Micotil® 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:

- Administration Recommendations
- 2. Usage Guidelines
- 3. Micotil Shroud and Sekurus Syringe
- 4. Administration Technique
- 5. Micotil® How to Shroud Video



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® 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®
- It is recommended that Micotil® 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





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



Module 3: Safe Handling and Administration

Micotil® Bottle Shroud and SekurusTM 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 800-362-2014.



Module 3: Safe Handling and Administration

Micotil® Bottle Shroud

- All product information contained in accordion style label on Micotil® 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



Module 3: Safe Handling and Administration

Micotil® Bottle Shroud- Use Instructions

- 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. Micotil[®] should only be administered with the quick-fit connector made specifically for its use along with the tube-fed safety syringe.
- Locate the two tamper-evident tabs at the base of the shroud. Twist and break them off.
- 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.
- Remove the flexible cap and push the guick-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.
- 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.

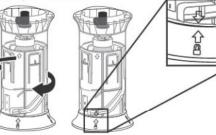
Administer only with a tube-fed safety syringe, Do not use in automatically powered syringes, single-use syringes, or other delivery devices. This product must be used with the quick-fit connector made specifically for use with Micotil (tilmicosin injection) that attaches to the shroud fitting. To obtain 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



Rotate the Shroud Top through a quarter-turn clockwise. The spike the confirmed by the alignment of will pierce the vial closure, and the the 2 arrows as shown in



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.



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









Module 3: Safe Handling and Administration

SekurusTM **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



Module 3: Safe Handling and Administration

SekurusTM **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.



Module 3: Safe Handling and Administration

SekurusTM **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.





Module 3: Safe Handling and Administration

SekurusTM **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



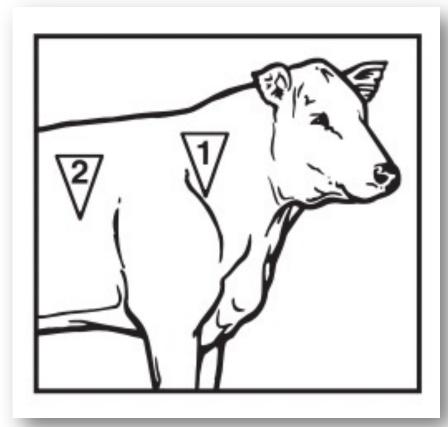




Module 3: Safe Handling and Administration

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)



Module 3: Safe Handling and Administration

Micotil® How to Shroud Video

For a video demonstration of how to use the Micotil® 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=jbKsKgCsI44



Module 3: Safe Handling & Administration

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

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

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



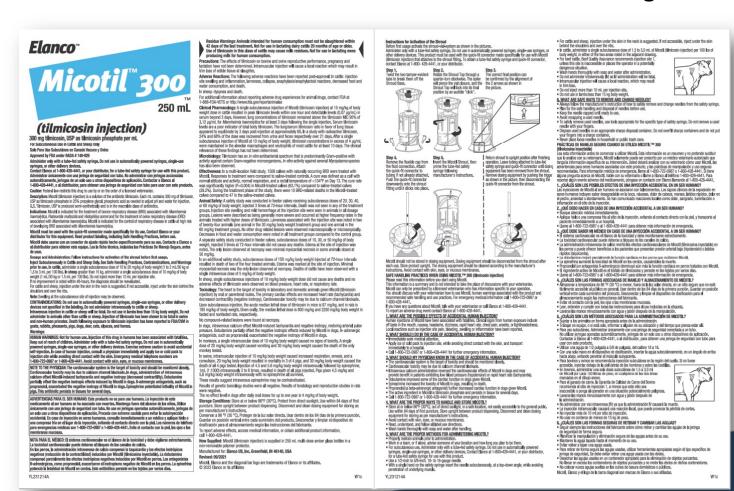
Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning

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



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



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.



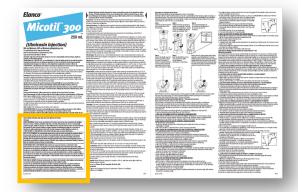
Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning

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. 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.





Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® 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.

Thank you for completing the Micotil® (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® 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.

For questions regarding Micotil® or this Safety Course, please contact your Elanco Sales Representative or call 800-362-2014.

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