



Micotil[®] 300 (tilmicosin injection)

Safety Course

Right for cattle. Right by you.

Elanco[™]

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®.

The Elanco logo consists of the word "Elanco" in a white, sans-serif font, slanted upwards to the right, set against a blue rectangular background. A small "TM" trademark symbol is located at the bottom right of the blue background.

PM-US-23-0846(3)

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

PM-US-23-0846(3)

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 140-221

Administer only with tubed safety syringe. Do not use an automatically powered syringe, single-use syringe, or other delivery device.

Contact Elanco at 1-800-428-4441, or your distributor for a tube-fed safety syringe for use with this product. Administer into a jug or juglet of segregated cow milk. Do not use for injection. See the instructions for use for details on jug and juglet use.

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

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

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

Micotil debe usarse con un conector de rápida eliminación específicamente para su uso. Contacte a Elanco o a distribuidor para obtener este equipo. Lea la Hoja de Datos, incluidas las Prácticas de Manejo Seguro, antes de usarlo.

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

Inject Subcutaneous in Cattle and Sheep Only. See Safe Handling Practices, Contraindications, and Warnings prior to use. In cattle, administer a single subcutaneous dose of 10 to 20 mg/kg of body weight (1 to 2 mL/50 to 1.5 to 3 mL per 100 lbs). In sheep greater than 15 kg, administer a single subcutaneous dose of 10 mg/kg of body weight (1.0 mL/20 to 1.5 mL per 100 lbs). Do not inject more than 10 mL per injection site.

If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

For cattle and sheep, inject under the skin in the neck as suggested. If not accessible, inject under the skin behind the shoulder and over the ribs.

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

CONTRAINDICATIONS: Do not use an automatically powered syringe, single-use syringe, or other delivery device not specified in the labeling. Do not administer intravenously to cattle or sheep.

Intravenous injection in cattle or sheep will be fatal. Do not use in lambs less than 15 kg body weight. Do not administer to animals other than cattle or sheep. Injection of Micotil has been shown to be fatal in swine and non-ruminant primates. Death following exposure to Micotil has been reported to FALCOW in goats, rabbits, ferrets, pigs, dogs, deer, cats, alligators, and horses.

Warnings:

HUMAN WARNINGS: 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 an automatically powered syringe, single-use syringe, or other delivery device. Exercise caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply oral or cold pack to injection site while awaiting direct contact with skin. Emergency medical telephone numbers are 1-800-722-5887 or 1-800-428-4441. Avoid contact with skin, eyes, or mucous membranes.

NOTE TO THE VETERINARIAN: The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to sudden elevated blood pressure. Discontinue administration of tilmicosin if clinical effects of the negative inotropic and negative inotropic (decreased contractility), debilitated output, or other effects of the negative inotropic of Micotil in dogs. 6-fermenting substrates, such as propylene glycol, exacerbated the negative inotropic of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.

ADVERTENCIAS PARA EL SER HUMANO: Este producto no es para uso humano. La inyección de este medicamento al ser humano no se asocia con mortalidad. Mantenga fuera del alcance de los niños. Utilice únicamente con una jeringa de seguridad con tubo. No use una jeringa o dispositivo de aplicación, jeringa de auto-inyección, inyección en un solo uso u otros dispositivos de aplicación. Procure con extrema cautela para evitar la auto-inyección accidental. En caso de inyección en seres humanos, consulte inmediatamente a un médico y aplique hielo o una compresa fría en el lugar de la inyección, evitando el contacto directo con la piel. Lea el número de teléfono para emergencias médicas con el 1-800-722-5887 o 1-800-428-4441. Evite el contacto con la piel, los ojos o las membranas mucosas.

NOTA PARA EL MEDICO: El sistema cardiovascular es el blanco de la toxicidad y debe vigilarse estrechamente. La toxicidad cardiovascular puede deberse al aumento de la presión de la sangre. Detenga la administración de tilmicosin si se observan efectos clínicos de la toxicidad cardiovascular, como disminución de la contractilidad cardíaca y otros efectos inotrópicos negativos (reducción de la contractilidad cardíaca y otros efectos inotrópicos negativos). La debilitación (disminución de la contractilidad cardíaca) y otros efectos inotrópicos negativos de Micotil en perros. Los fermentos 6-fermentantes, como el propilenglicol, exacerbaron los efectos inotrópicos negativos de Micotil en perros. La epinefrina potenció la letalidad de Micotil en cerdos. Este antibiótico persiste en los tejidos por varios días.

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

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

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

In sheep: dyspnea and death.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-800-FDA-VEIS or <http://www.fda.gov/medwatch>.

Clinical Pharmacology: A single subcutaneous injection of Micotil (tilmicosin injection) at 10 mg/kg of body weight dose in cattle resulted in peak tilmicosin levels within one hour and detectable levels (0.07 µg/mL) in serum beyond 3 days. However, lung concentrations of tilmicosin remained above the MIC (MIC 50% of 3.12 µg/g) for Mannheimia haemolytica for at least 3 days following the single injection. Serum tilmicosin levels are a poor indicator of total body tilmicosin. The lung:serum tilmicosin ratio in favor of lung tissue appeared to equilibrate by 3 days post-injection at approximately 0.3. In a study with radiolabeled tilmicosin, 24% and 58% of the dose was recovered from urine and feces respectively over 21 days. After a single subcutaneous injection of Micotil at 10 mg/kg of body weight, tilmicosin concentrations in excess of 1 µg/mL were maintained in the alveolar macrophage population of most cattle for at least 10 days. The clinical relevance of these findings has not been determined.

Microbiology: Tilimicosin has an in vitro antibacterial spectrum of most cattle for at least 10 days. The clinical relevance of these findings has not been determined.

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. Death was not seen in any of the treatment groups. Decreases in feed intake and milk hemorrhage at the injection site were seen in animals of all dosages. Lesions were described as being generally more severe and occurred at higher frequency rates in the animals treated with higher dosages. Lesions associated with the injection site was noted in two of ten 40-mg animals (one animal in the 30 mg/kg body weight treatment group and one animal in the 60 mg/kg treatment group). No other drug related lesions were observed macroscopically or microscopically. Decreases in feed and water consumption were noted in all treatment groups compared to the control group. A separate safety study conducted in feeder calves, subcutaneous doses of 10, 30, or 50 mg/kg of body weight, injected 3 times at 72-hour intervals did not cause any deaths. Edema at the site of injection was noted. The only lesions observed at necropsy was minimal myocardial necrosis in some animals dosed at 20 mg/kg.

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.

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 animal species. Micotil (tilmicosin injection) by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropic). 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. In goats, the median lethal dose is 800 mg/kg and 2250 mg/kg body weight in fed and fasted rats, respectively.

No compound-related lesions were found at necropsy.

In dogs, intravenous calcium effect: Micotil-induced tachycardia and negative inotropic, restoring arterial pulse pressure. Occurrence partially offset the negative inotropic effect induced by Micotil in dogs. In a subacute irritable, such as propylene glycol, exacerbated the negative inotropic of Micotil in dogs.

In monkeys, a single intramuscular dose of 10 mg/kg body weight caused no signs of toxicity. A single dose of 50 mg/kg body weight caused lethality and 20 mg/kg body weight caused the death of a monkey. Lethal.

In swine, intramuscular injection of 10 mg/kg body weight caused increased respiration, emesis, and a convulsion. 20 mg/kg body weight resulted in mortality in 3 of 4 pigs, and 30 mg/kg body weight caused the death of 4 of 4 pigs tested. Injection of 4.5 and 5.0 mg/kg body weight body weight followed by epinephrine, 1 mg, 1:1000 intravenously 2 to 8 minutes, resulted in 0 of 4 pigs injected, but 100% 4 mg/kg and 5.0 mg/kg body weight intravenously with no epinephrine all survived.

These results suggest intravenous epinephrine may be beneficial in deaths.

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

The effect of feed in dogs after daily oral doses for up to one year is a mg/kg of body weight.

Storage Conditions: Store at or below 86°F (30°C). Protect from direct sunlight. Use within 64 days of first puncture. Store upright between product dispensing and cleaning and dispensing equipment for storage or manufacturer's instructions.

Conserve at 86°F (30°C). Protégelo de la luz solar directa. Use dentro de los 64 días de la primera punción. Guarde el frasco vertical entre cada administración del producto. Desinfecte y limpie el dispositivo de dosificación para su uso o instrucciones del fabricante.

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

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

Manufacturer: Elanco Inc., Greenfield, IN 46940, USA

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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-kill connector made specifically for use with Micotil (tilmicosin injection) that attaches to the shroud fitting. To activate a tube-fed safety syringe and quick-kill connector, contact Elanco at 1-800-428-4441, or your distributor.

Step 1: Pull the 2 large-vented tubes through a quarter-bar discharge. The spike will pierce the seal around the Shroud Top will lock into its final position in a "stable" "lock".

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

Step 3: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 4: Remove the flexible cap from the fluid connector. Attach the tube-fed safety syringe to the quick-kill connector. Push the quick-kill connector downwards onto the shroud fitting until it clicks into place.

Step 5: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 6: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 7: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 8: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 9: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 10: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 11: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 12: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 13: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 14: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 15: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 16: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 17: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 18: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 19: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 20: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 21: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 22: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 23: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 24: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 25: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 26: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 27: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 28: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 29: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 30: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 31: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 32: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 33: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 34: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 35: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 36: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 37: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 38: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 39: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 40: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 41: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 42: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 43: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 44: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 45: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 46: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 47: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 48: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 49: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 50: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 51: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 52: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 53: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 54: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 55: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 56: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 57: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 58: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 59: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 60: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 61: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 62: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

Step 63: Press the Micotil Shroud, then prime the tube-fed safety syringe. Follow the manufacturer's instructions.

Step 64: Return shroud to upright position after finishing operation. Leave tubing attached to tube-fed safety syringe and quick-kill connector until dosing equipment has been removed from the shroud. Remove dosing equipment by pulling the trigger in the shroud. Then disconnect the quick-kill connector from the shroud fitting and it clicks into place.

For cattle and sheep, inject under the skin in the neck as suggested. If not accessible, inject under the skin behind the shoulder and over the ribs.

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

For feed cattle, feed quality Assurance recommends injection site 1 unless 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 fluid connector. Intramuscular injection will cause a local reaction, which may result in loss of edible tissue at the site.

Do not use in lambs less than 15 kg body weight.

WHAT ARE SAFE WAYS TO REMOVE AND CHANGE NEEDLES?

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

Ben for safe handling of needles and needles before use.

Keep the needle capped until ready to use.

Avoid recapping a used needle.

Dispose of needles in an appropriate sharps disposal container. Do not overfill sharps containers and do not put your fingers into a sharps container.

Never reuse needles in an appropriate sharps disposal container or public trash cans.

PRÁCTICAS DE MANEJO SEGURO CUANDO SE UTILIZA MICOTIL™ 300 (tilmicosin inyección)

Las siguientes instrucciones de cómo comenzar a utilizar Micotil. Esta información es un resumen y no pretende sustituir lo que se indica con el veterinario. Micotil solamente puede ser prescrito por un médico veterinario autorizado que tenga información específica de su intervención. Antes de comenzar a utilizar este medicamento consulte con su veterinario cómo usar Micotil. Lea las advertencias para ser un usuario asociado con este producto, y las prácticas de manipulación y uso seguro recomendadas. Para información médica de emergencia, llame al 1-800-722-5887 o 1-800-428-4441. Si tiene alguna pregunta acerca de Micotil, hable con su veterinario o llame a Elanco al teléfono 1-800-428-4441. Para reportar algún evento adverso del medicamento, póngase en contacto con Elanco Biomark al 1-800-428-4441.

1. ¿CUÁLES SON LOS POSIBLES EFECTOS DE UNA INYECCIÓN ACCIDENTAL EN UN SER HUMANO?

La inyección de Micotil al ser humano se asocia con toxicidad. Los signos clínicos de la exposición en seres humanos incluyen dispareunia, náusea, vómitos, dolor de cabeza, mareos, dolor de estómago. Antes de reportar, debe en el punto, administrar el medicamento. Se ha comunicado reacciones locales como dolor, sangrado, lumbalgia o inflamación o el sitio de la inyección.

2. ¿QUE DEBE HACER EN CASO DE UNA INYECCIÓN ACCIDENTAL EN UN SER HUMANO?

Si se administra erróneamente a un ser humano, debe ser prescrito por un médico veterinario autorizado que tenga información específica de su intervención. Antes de comenzar a utilizar este medicamento consulte con su veterinario cómo usar Micotil. Lea las advertencias para ser un usuario asociado con este producto, y las prácticas de manipulación y uso seguro recomendadas. Para información médica de emergencia, llame al 1-800-722-

Micotil® 300 (tilmicosin injection) Safety Course

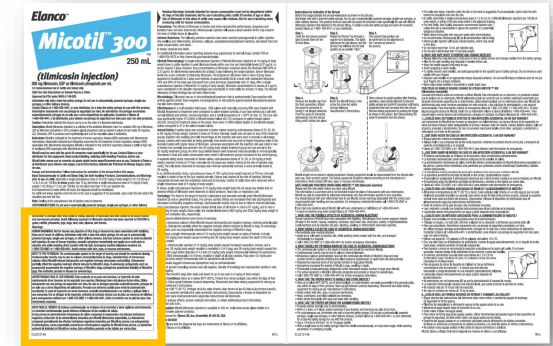
Module 1: Micotil® Overview and User Expectations

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. β -adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.



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PM-US-23-0846(3)

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 covered 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 top-down angle while avoiding penetration of underlying muscles.
- 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 pack
- REFERENCE** product label and provide to emergency 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 use of needles, syringes, and other delivery devices. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and report to your local poison control center 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 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 older than 20 months of age or older than 18 months in any other species. Horses that have been reported to react to injectable antibiotics should be monitored closely. The following adverse reactions have been reported in cattle: injection site swelling and induration; depression; colic; respiratory/arthropathic reactions; reticulated forest and under-forelimbs; and death. Horses have been reported to have fatal reactions within 24 hours.

Elanco Micotil® 300 (Tilmicosin Injection) 250 mL

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Chute Side Poster

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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 by children and the general public.
- 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 18-gauge needle.
- Keep a protective cover on needles until ready to use.
- Never carry loaded syringes in pocket or clothing.
- Wash hands thoroughly with soap and water after handling.
- Access to Micotil should be limited to personnel trained in safe handling and use procedures.

WHAT TO DO IN CASE OF SELF-INJECTION

Seek immediate medical attention and:

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

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 FIRST AID EQUIPMENT

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Client Dispensing Information

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Micotil[®] (tilmicosin injection) Safety Course

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[®].

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PM-US-23-0846(3)

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



Micotil[®] (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[®] (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[®] (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[™] 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[®] (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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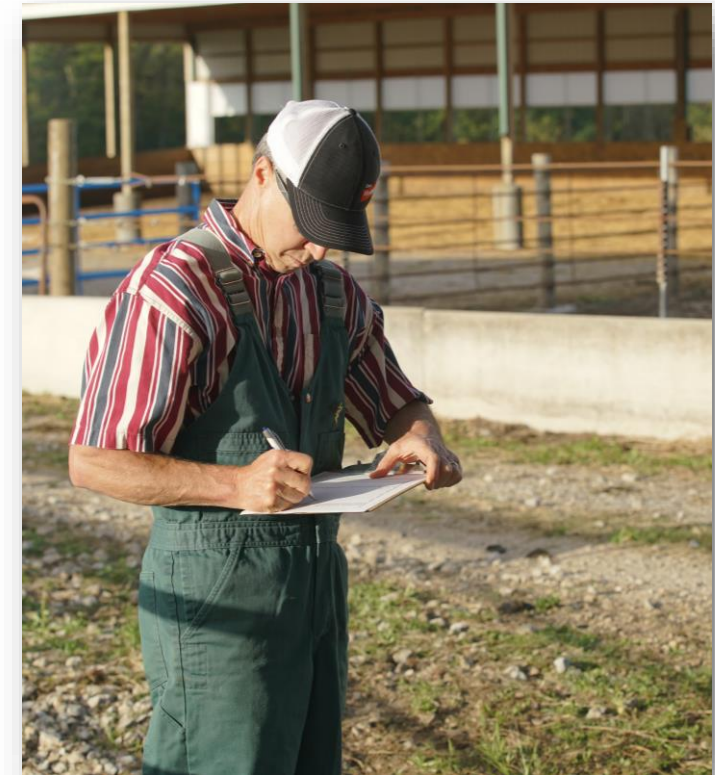
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Micotil[®] (tilmicosin injection) Safety Course

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

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"0" to 3"10" 18- or 16-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 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 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 injection, contact a physician immediately and apply eye or nose patch to prevent self-injection. Avoid contact with the drug. Avoid contact with eyes.

Always use proper drug handling procedures to avoid accidental self-injection. Consult your veterinarian on the safe handling and use of all injectable products prior to administration. For use in cattle—always only inject subcutaneously. Exposure to this antineoplastic has been shown to be toxic to aquatic and non-aquatic organisms, and may be toxic to insects and birds. Do not use in human dairy cattle 30 months of age or older. Use in weaned dairy cattle or sheep may cause milk resistance. The following adverse reactions have been reported in cattle: reactions to handling and information, tremors, colic, anorexia, respiratory/acidotic metabolic disease, increased food and water consumption, and death. Micotil has a withdrawal time of 60 days.

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Chute Side Poster

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Micotil[®] (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	REFERENCE	REMEMBER
for and apply ice pack	product label and provide to emergency medical personnel	to call SafetyCall at 800-722-0987 or Elanco at 800-428-4441

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Micotil[®] (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[®].

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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:

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

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Micotil[®] (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[®] 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



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Micotil[®] (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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Micotil[®] (tilmicosin injection) Safety Course

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



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Micotil[®] (tilmicosin injection) Safety Course

Module 3: Safe Handling and Administration

Micotil[®] Bottle Shroud- Use Instructions

1. Gather materials to administer Micotil[®]. Materials needed include the 250 ml product bottle encased in the protective shroud, a tube-fed safety syringe and an appropriately sized needle for subcutaneous injection. Micotil[®] 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.

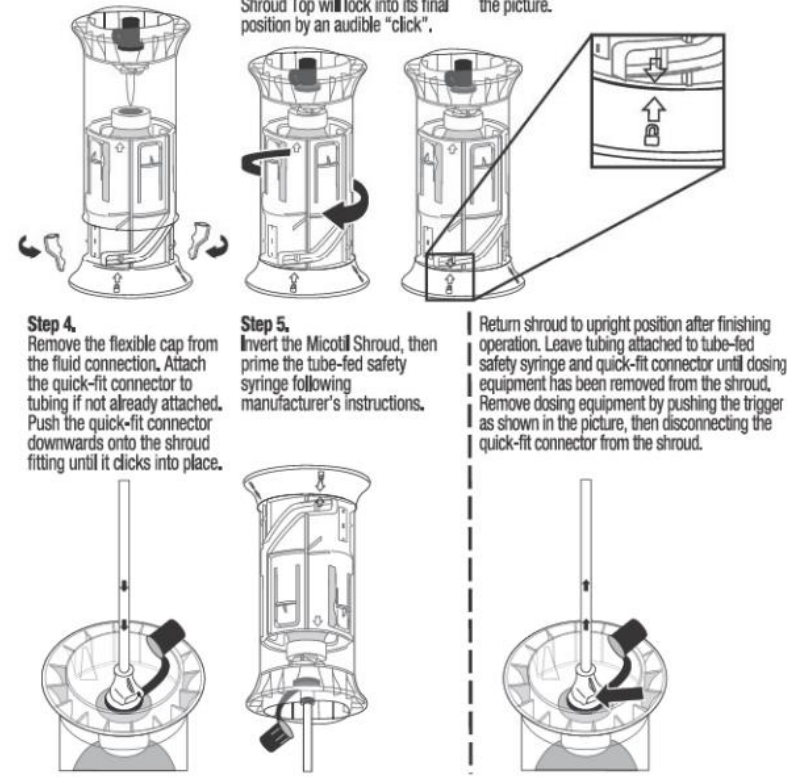
Step 2. Rotate the Shroud Top through a quarter-turn clockwise. The spike will pierce the vial closure, and the Shroud Top will lock into its final position by an audible "click".

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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PM-US-23-0846(3)

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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PM-US-23-0846(3)

Micotil[®] (tilmicosin injection) Safety Course

Module 3: Safe Handling and Administration

Sekurus[™] 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[®] (tilmicosin injection) Safety Course

Module 3: Safe Handling and Administration

Sekurus[™] 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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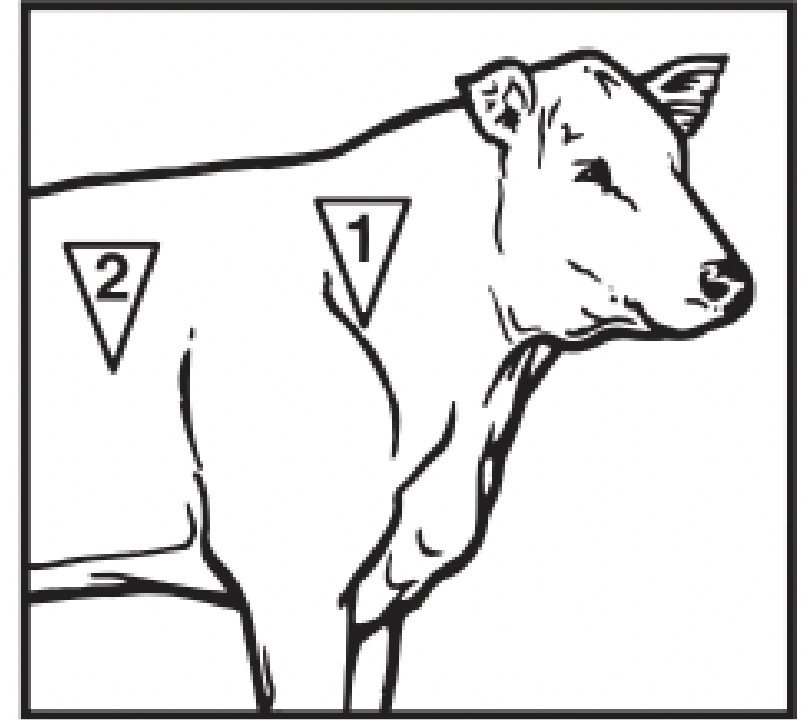
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Micotil[®] (tilmicosin injection) Safety Course

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[®] (tilmicosin injection) Safety Course

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=jbKsKgCsl44>



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Micotil[®] (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[®] .

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.

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Micotil®
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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

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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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Micotil® 300 (tilmicosin injection) Safety Course

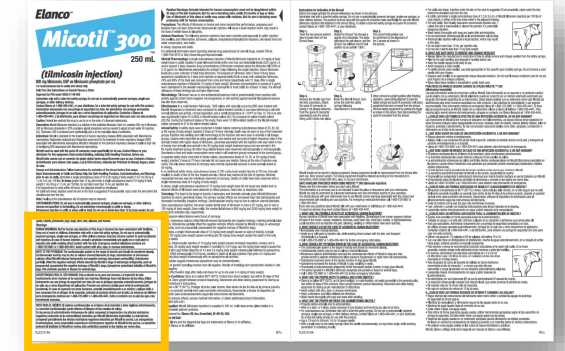
Module 4: Micotil® Storage Recommendations, Review of Micotil® Label Indications and Micotil® Boxed Warning

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. β -adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.



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Micotil[®] (tilmicosin injection) Safety Course

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.

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Micotil[®] (tilmicosin injection) Safety Course

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 800-428-4441.

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