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**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**

ELANCO AH0230

Micotil®
300 Injection
(Tilmicosin) *

ACTIVE CONSTITUENT: 300 mg/mL TILMICOSIN
(as tilmicosin phosphate)

For use in lot-fed cattle for the treatment of
Bovine Respiratory Disease (BRD) associated
with *Mannheimia (Pasteurella) haemolytica*,
Pasteurella multocida, and other organisms
susceptible to tilmicosin.

For Subcutaneous Injection Only in Cattle
APVMA approval No. 45653/100mL/0704

Manufactured in UK for:
ELANCO ANIMAL HEALTH,
A division of Eli Lilly Australia Pty Limited
Tel: Toll Free 1800 226 324

100 mL

READ ENCLOSED LEAFLET BEFORE USING THIS PRODUCT.

DIRECTIONS FOR USE:

Restraints:

DO NOT USE in lactating cows where milk or milk products may be used for human consumption.

Contraindications and Precautions: Refer enclosed leaflet.

Dosage and Administration:

Administer a single subcutaneous injection of 10 mg tilmicosin/kg bodyweight (1 mL per 30 kg) high into the neck. Do not exceed 25 mL per injection site.

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease, or target species may require extending the approved withholding period.

WITHHOLDING PERIODS:

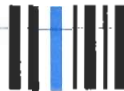
MEAT - DO NOT USE less than 28 days before slaughter for human consumption.

MILK - DO NOT USE in lactating cows where milk or milk products may be used for human consumption.

FIRST AID: HUMAN WARNINGS: Not for human use. Injection of this drug in humans has been associated with fatalities. Keep out of reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a doctor or Poisons Information Centre (13 1126) immediately and apply ice to injection site. Avoid contact with eyes.

Note to doctor: For important information on accidental human injection refer outer carton or enclosed leaflet.

*Elanco®, Micotil® and the diagonal colour bar are trademarks of Eli Lilly and Company.



Store below 30°C
(Room Temperature).
Protect from direct
sunlight.

Batch No.:
Expiry Date:

YL00320EAL (1-JUL-04)

APVMA
APPROVED
LABEL
COPY

SH8012DEALS
(1-JUL-04)

Expiry Date:

Batch No.:

Store below 30°C (Room Temperature)
Protect from direct sunlight. Use the
contents of the vial within 90 days of initial
breaching and discard any unused portion

100 mL *

Micotil®
300 Injection
(Tilmicosin)

ELANCO • AH0230

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled "sharps" container.

APVMA Approval No: 45653/100mL/0704

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DIRECTIONS FOR USE:

Restraints:

DO NOT USE in lactating cows where milk or milk products may be used for human consumption.

Contraindications and Precautions:

This product must not be administered intravenously or intramuscularly.

Inject subcutaneously only in cattle. Intravenous injection in cattle has been fatal.

This product is contraindicated for use in pigs. Injection in pigs has been fatal.

Pneumatic or hydraulically operated syringes should not be used with this product.

Dosage and Administration:

Administer a single subcutaneous injection of 10mg tilmicosin/kg bodyweight (1mL per 30kg), using a standard disposable syringe or multi-filling syringe. Do not inject more than 25mL per injection site. Subcutaneous injection must be made high into the neck. If no improvement is noted within 48 hours the diagnosis should be re-evaluated.

FIRST AID: HUMAN WARNINGS: Not for human use. Injection of this drug in humans has been associated with fatalities. Keep out of reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a doctor or Poisons Information Centre (13 1126) immediately and apply ice to injection site. Avoid contact with eyes. (For "Note to doctor" see side panel).

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease, or target species may require extending the approved withholding period.

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ELANCO * AH0230

Micotil®
300 Injection
(Tilmicosin) *

ACTIVE CONSTITUENT:
300 mg/mL TILMICOSIN
(as tilmicosin phosphate)

For use in lot-fed cattle for the treatment of Bovine Respiratory Disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica*, *Pasteurella multocida*, and other organisms susceptible to tilmicosin.

For Subcutaneous Injection Only in Cattle

Manufactured in U.K. for: **100 mL**
ELANCO ANIMAL HEALTH

A division of Eli Lilly Australia Pty Limited
ABN 39 000 233 992

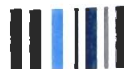
112 Wharf Road, West Ryde N.S.W. 2114
Tel Toll Free 1800 226 324

Note to doctor:

The cardiovascular system is the target of toxicity and should be monitored closely. This antibiotic persists in tissues for several days. Apply ice to injection site and provide supportive treatment. Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. β -adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil-induced tachycardia in dogs.



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ELANCO* AH0230

Micotil® 300 Injection
(Tilmicosin)

INDICATIONS: Micotil is indicated for the treatment of respiratory diseases (BRD) in lot-fed cattle associated with *Mannheimia (Pasteurella) haemolytica* and *P. multocida*, and other organisms sensitive to tilmicosin.

DESCRIPTION: Micotil is a solution of the antibiotic tilmicosin. Each mL contains 300 mg of tilmicosin (as tilmicosin phosphate); 25% propylene glycol; phosphoric acid as needed to adjust pH; water for injection, q.s. Tilmicosin is produced semi-synthetically and is a member of the macrolide class of antibiotics.

ACTIONS: Activity: Tilmicosin has an *in vitro* bacteriostatic antibacterial spectrum that is predominantly gram-positive with activity against certain gram-negative microorganisms. Activity against several mycoplasma species has also been detected.

Ninety five percent of the *Mannheimia (Pasteurella) haemolytica* isolates were inhibited by 3.12 µg /mL or less. For *P. multocida*, the MIC 95% was 6.25 µg /mL or less.

Microorganisms	MIC (µg/mL)
<i>Mannheimia (Pasteurella) haemolytica</i>	3.12
<i>Pasteurella multocida</i>	6.25
<i>Haemophilus somnus</i>	6.25
<i>Staphylococcus aureus</i>	0.78
<i>Streptococcus agalactiae</i>	3.12
<i>Arcanobacterium pyogenes</i>	0.024
<i>Clostridium perfringens</i>	3.12
<i>Clostridium sordellii</i>	3.12
<i>Fusobacterium necrophorum</i>	3.12
<i>Escherichia coli</i>	>50.00
<i>Salmonella typhimurium</i>	>50.00
<i>Mycoplasma dispar</i>	0.097
<i>Mycoplasma bovirhinis</i>	0.024
<i>Mycoplasma bovoculi</i>	0.048
<i>Acholeplasma laidlawii</i>	0.024

In clinical trials, BRD treatment success with Micotil was usually characterised by rapid reduction in body temperatures, reduced severity of clinical signs, increased weight gains and reduced mortality.

TOXICOLOGY: The heart is the target of toxicity in laboratory and domestic animals given MICOTIL 300 by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy).

Upon injection subcutaneously, the acute median lethal dose of tilmicosin in mice is 97 mg/kg, and in rats is 185 mg/kg of bodyweight. Given orally, the median lethal dose is 800 mg/kg and 2250 mg/kg in fasted and nonfasted rats respectively. No compound-related lesions were found at necropsy.

In monkeys, a single intramuscular dose of 10 mg/kg caused no signs of toxicity. A single dose of 20 mg/kg caused vomiting and 30 mg/kg caused the death of the only monkey tested.

In pigs, intramuscular injection of 10 mg/kg caused increased respiration, emesis, and a convulsion, 20 mg/kg resulted in mortality in 3 of 4 pigs, and 30 mg/kg caused the death of all 4 pigs tested.

Results of genetic toxicology studies were all negative. Results of teratology and reproduction studies in rats were negative. The no effect level in dogs after daily oral doses for up to one year is 4 mg/kg of bodyweight.

In cattle, subcutaneous doses of 10, 30 and 50 mg/kg of bodyweight, each injected three times at 72 hour intervals did not cause any deaths. As expected oedema at the site of injection was noted. The only lesion observed at necropsy was minimal myocardial necrosis in some animals in the 50 mg/kg group. Subcutaneous doses of 150 mg/kg injected at 72 hour intervals resulted in deaths.

Oedema 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 bodyweight.

Clinical Absorption and Excretion: A single subcutaneous injection of Micotil at 10 mg/kg of bodyweight in cattle resulted in peak tilmicosin levels within one hour, and detectable levels in serum beyond 3 days. However, lung concentrations of tilmicosin remained above the tilmicosin MIC 95% of 3.12 µg /mL for *M. haemolytica* for at least three days following the single injection. Serum tilmicosin levels are a poor indicator of total body tilmicosin. The lung/serum tilmicosin ratio in favour of lung tissue appeared to equilibrate by three days post injection at approximately 60. In a study with radioactive tilmicosin, 24% and 68% of the dose was recovered from urine and faeces respectively over 21 days.

DIRECTIONS FOR USE:

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If no improvement is noted within 48 hours, the diagnosis should be re-evaluated.

NOTE: Swelling at the subcutaneous site of injection may be observed but is transient and usually mild.

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Note to doctor: The cardiovascular system is the target of toxicity and should be monitored closely. This antibiotic persists in tissues for several days. Apply ice to injection site and provide supportive treatment. Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs.

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APVMA Approval No: 45653/100mL/0704

Storage: Store below 30° C (Room Temperature). Protect from direct sunlight. Use the contents of the vial within 90 days of initial broaching and discard any unused portion.

Presentation: Micotil is supplied in 100 mL multidose amber bottles containing 300 mg/mL tilmicosin (as tilmicosin phosphate).

Manufactured in U.K. for:

Elanco Animal Health

A Division of Eli Lilly Australia Pty Limited

ABN 39 000 233 992

112 Wharf Road, West Ryde, NSW 2114

Tel: Toll Free 1800 226 324

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