

 **Draxxin**[™]
(tulathromycin)
Injectable Solution

Antibiotic
100 mg of tulathromycin/mL

For subcutaneous injection in beef and non-lactating dairy cattle and intramuscular injection in swine only.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS

Cattle
DRAXXIN Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*), and for the control of respiratory disease in cattle at high risk of developing BRD, associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*).

Swine
DRAXXIN Injectable Solution is indicated for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica* and *Haemophilus parasuis*.

DOSAGE AND ADMINISTRATION

Cattle
Inject subcutaneously as a single dose in the neck of cattle at a dosage of 2.5 mg/kg (1.1 mL/100 lb) body weight (BW). Do not inject more than 10 mL per injection site.

Swine
Inject intramuscularly as a single dose in the neck of swine at a dosage of 2.5 mg/kg (0.25 mL/22 lb) BW. Do not inject more than 2.5 mL per injection site.

CONTRAINDICATIONS

The use of DRAXXIN Injectable Solution is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS

**FOR USE IN ANIMALS ONLY. NOT FOR HUMAN USE.
KEEP OUT OF REACH OF CHILDREN.
NOT FOR USE IN CHICKENS OR TURKEYS.**

RESIDUE WARNINGS

Cattle
Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Swine
Swine intended for human consumption must not be slaughtered within 5 days from the last treatment.

PRECAUTIONS

Cattle
The effects of DRAXXIN on bovine reproductive performance, pregnancy and lactation have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

Swine
The effects of DRAXXIN on porcine reproductive performance, pregnancy and lactation have not been determined. Intramuscular injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS

Cattle
In one field study, two calves treated with DRAXXIN at 2.5 mg/kg BW exhibited transient hypersalivation. One of these calves also exhibited transient dyspnea, which may have been related to pneumonia.

Swine
In one field study, one out of 40 pigs treated with DRAXXIN at 2.5 mg/kg BW exhibited mild salivation that resolved in less than four hours.

STORAGE CONDITIONS

Store at or below 25°C (77°F)

HOW SUPPLIED

DRAXXIN Injectable Solution is available in the following package sizes
100 mL vial
250 mL vial
500 mL vial

U.S. Patents: See US 6,329,345; US 6,420,536; US 6,514,945; US 6,583,274; US 6,777,393

NADA 141-244, Approved by FDA

 **Pfizer Animal Health**
Division of Pfizer Inc, NY, NY 10017

To report a suspected adverse reaction call 1-800-366-5288.
To request a material safety data sheet call 1-800-733-5500.
For additional DRAXXIN product information call:
1-888-DRAXXIN or go to www.DRAXXIN.com

TAKE
TIME  OBSERVE LABEL
DIRECTIONS

79-9947-00-0
March 2005



Guidelines for Authors

The Bovine Practitioner is the official publication of The American Association of Bovine Practitioners, published in February and June annually. It also serves as a communication medium between bovine practitioner organizations around the world. All manuscripts and communications must be presented in English.

Most articles in the journal are peer-reviewed or refereed. Papers submitted for publication in the peer-reviewed section are anonymously reviewed by three members of the editorial board. In some cases, papers may be reviewed by an outside expert(s) who is not a regular member of the editorial board. Papers published in the peer-reviewed section of the journal will be identified with a "Peer-Reviewed" banner at the top of the first page. Papers rejected by the editorial board for publication as peer-reviewed articles do not automatically qualify for publication in the non-peer-reviewed sections.

Articles published in *The Bovine Practitioner* are intended to address the needs of bovine practitioners. Types of articles considered appropriate for the journal include research reports, case reports, review articles, retrospective studies and articles describing new techniques.

All papers should begin with an abstract. Research reports should follow with an introduction, materials and methods (including experimental design and statistical analysis), results, discussion and conclusions. At the author's discretion, results and discussion may be combined.

Case reports should be written to include an introduction, history, clinical findings, appropriate laboratory data, surgical/therapeutic management, discussion and conclusions.

Review articles covering topics important to the practitioner are welcome. They should address more recent advances and bring the reader cutting edge information related to bovine practice or to beef or dairy production.

Papers reporting retrospective studies should include an introduction, clinical implications or objectives of the study, the methodology used to evaluate the data, a section that details the significance of the findings to the practitioner and conclusions.

Two manuscripts and a diskette should be submitted to the editor through the mail or via a parcel delivery service. Manuscripts should be double-spaced, using 12-point Times type and 1-inch margins. Both lines and pages should be numbered. When possible Microsoft Word should be used.

Figures, tables and photographs are welcome. Figures should be numbered on the back: legends for figures should be submitted on a separate sheet of paper. When photographs are submitted, prints are preferred over 2x2 slides.

English units of measure should be used for weights, measures and temperature. If the author desires, it is acceptable to follow English units with metric units in parenthesis, i.e...440 lb (200 kg) steer had a rectal temperature of 101.5°F (38.6°C). When the use of brand names is necessary, they should be listed in footnotes, including the name of product, manufacturer, and manufacturer's city and state.

References to literature cited in the paper must be identified in the text by the use of superscripts. References should be listed in **alphabetical order**. Suggested style for citations in the reference section is as follows:

1. Allen WM, Sansom BF: Parturient paresis (milk fever) and hypocalcemia (cows, ewes, and goats), in Howard JL (ed): *Current Veterinary Therapy III. Food Animal Practice*. Philadelphia, WB Saunders Co, 1993, pp 304-308.
2. Barth AD, Cates WF, Harland RJ: The effect of body fat and loss of fat on breeding soundness classification of beef bulls. *Can Vet J* 36:758-764, 1995.
3. Nutrient Requirements of Beef Cattle, ed 7. Washington DC, National Academy Press, 1996.
4. Syvrud R: Vaccination for bovine respiratory syncytial virus: Benefits for both cow/calf and feedlot cattle. *Proc Am Assoc Bov Prac* 21:204-206, 1989.

All correspondence and manuscripts should be addressed to:

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Micotil® 300*

Tilmicosin Injection, USP

CAUTION: Federal (USA) 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. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice to injection site. Emergency medical telephone numbers are 1-800-722-0987 or 1-317-276-2000. Avoid contact with eyes.

NOTE TO THE PHYSICIAN: 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. Epinephrine potentiated lethality of Micotil in pigs. Dobutamine partially offset the negative inotropic effects induced by Micotil in dogs. β -adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil-induced tachycardia in dogs.

For Subcutaneous Use in Cattle and Sheep Only. Do Not Use in Automatically Powered Syringes.

Indications: Micotil 300 is indicated for the treatment of bovine respiratory disease (BRD) and ovine respiratory disease (ORD) associated with *Mannheimia (Pasteurella) haemolytica*. Micotil 300 is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*.

Description: Micotil 300 is a solution of the antibiotic tilmicosin. Each mL contains 300 mg of tilmicosin, USP as tilmicosin phosphate in 25% propylene glycol, phosphoric acid as needed to adjust pH and water for injection, Q.S. Tilmicosin, USP is produced semi-synthetically and is in the macrolide class of antibiotics.

Actions: Activity — Tilmicosin has an *in vitro*** 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 μ g/mL or less.

Microorganism	MIC** (μ g/mL)
<i>Mannheimia (Pasteurella) haemolytica</i>	3.12
<i>Pasteurella multocida</i>	6.25
<i>Haemophilus somnus</i>	6.25
<i>Mycoplasma dispar</i>	0.097
<i>M. bovirhinis</i>	0.024
<i>M. bovoculi</i>	0.048

**The clinical significance of this *in vitro* data in cattle and sheep has not been demonstrated.

Directions — Inject Subcutaneously in Cattle and Sheep Only. Administer a single subcutaneous dose of 10 mg/kg of body weight (1 mL/30 kg or 1.5 mL/100 lbs). Do not inject more than 15 mL per injection site. Do not use in lambs less than 15 kg body weight.

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

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.

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

CONTRAINDICATION: Do not use in automatically powered syringes. Do not administer intravenously to cattle or sheep. Intravenous injection in cattle or sheep will be fatal. Do not administer to animals other than cattle or sheep. Injection of this antibiotic has been shown to be fatal in swine and non-human primates, and it may be fatal in horses and goats.

WARNINGS: Animals intended for human consumption must not be slaughtered within 28 days of the last treatment. 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.

CAUTION: Read accompanying literature fully before use. Do Not Administer to Swine. Injection in Swine Has Been Shown to be Fatal. The safety of tilmicosin has not been established in pregnant cattle and in animals used for breeding purposes. Intramuscular injection will cause a local reaction which may result in trim loss. The safety of tilmicosin has not been established for sheep with a body weight of less than 15 kg or in pregnant sheep or sheep used for breeding purposes.

How Supplied: Micotil 300 is supplied in 50 mL, 100 mL and 250 mL multidose amber glass bottles.

Storage: Store at or below 86° F (30°C). Protect from direct sunlight.

Revised September 2003

Manufactured for:
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285, USA

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AH 0230
NADA 140-929. Approved by FDA
PA9041DEAMP

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Micotil

TM

Low treatment cost.

High value.



One 250 mL bottle of Micotil® (tilmicosin injection) treats 33 calves at a cost that's 39 percent less/head than any major premium competitor!

¹Based on 500-lb calf; current market price as compared to the combined average treatment cost of Nulflor® (florfenicol), Baytril® (enrofloxacin), A180® (danofloxacin mesylate), Excenel™ (ceftiofur hydrochloride), Naxcel® (ceftiofur sodium) and Excede™ (ceftiofur crystalline free acid). Market price may vary.

²Apley M. *Food Animal Practice*. 13:559-562, 1997.

³Fossler, SC. Elanco Animal Health, Study T5C760004, *Micotil Tech Report A18916*, 2001.

⁴Fossler SC, et al. *Proceedings of the 81st Annual Meeting of the Conference of Research Workers in Animal Diseases*, p.101, Nov. 12-18, 2000.

⁵Mechor GD. Elanco Animal Health, Study T5CB30206, *Micotil Tech Report A18758*.

⁶Mechor GD, et al. Elanco Animal Health, Study T5CB30107, *Micotil Tech Report A19476*.

⁷Bateman KG, et al. *Can Vet J* 31:689-696, 1990.

⁸Morck DW, et al. *J Am Vet Med Assoc* 202:273-277, 1993.

When a product consistently performs well for your clients, and its application is both easy for them and easy on their cattle, you might expect it to cost as much or more than the competition. Micotil is clearly different, and it's a difference that may surprise you. Here's the bottom line — your clients can spend about \$10 to \$14 per treatment for other premium products (\$13 is the combined average¹) or you can prescribe a 250 mL bottle of Micotil that treats 33 head for just under \$8 per treatment. So when it comes to helping your clients boost their bottom line, be sure to compare price tags... both sides of the tag.

Micotil is to be used by, or on the order of, a licensed veterinarian. For cattle, inject subcutaneously. Intravenous use in cattle will be fatal. Do not use in female dairy cattle 20 months of age or older. Use in lactating dairy cattle may cause milk residues. See label for complete use information, including human warnings. Always use proper drug handling procedures to avoid accidental self-injection.

Please remember to advise your clients on the safe handling and use of all injectable products prior to administration.

For product label, including boxed warning, see adjacent page.

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Micotil
Tilmicosin injection

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Introducing Draxxin.TM

The first-line, single-dose BRD treatment you've always wanted.



- DRAXXINTM (tulathromycin) Injectable Solution is a unique, new, single-dose therapy for the first-line treatment of BRD
- DRAXXIN's low-volume dose is highly effective against all three major BRD pathogens
- DRAXXIN consistently delivers higher treatment success than Nuflor[®] 1,2,3
- DRAXXIN improves profitability by significantly reducing mortality, chronics and repulls, resulting in more pounds of beef at closeout 1,2,3

Do not use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. Effects on reproductive performance, pregnancy and lactation have not been determined.

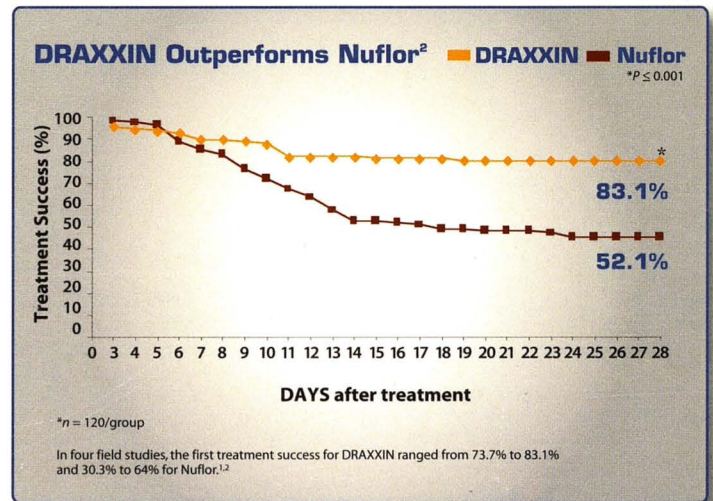
For more information, contact your veterinarian or local Pfizer representative, or call 1-888-DRAXXIN. www.DRAXXIN.com

¹ Skogerboe TL, Rooney KA, Nutsch RG, Weigel DJ, Gajewski K, Kilgore WR. Comparative efficacy of tulathromycin versus florfenicol and tilmicosin against undifferentiated bovine respiratory disease in feedlot cattle. *Vet Ther* 2005; 6(2): 180-196.

² Nutsch RG, Skogerboe TL, Rooney KA, Weigel DJ, Gajewski K, Lectenberg KF. Comparative efficacy of tulathromycin, tilmicosin, and florfenicol in the treatment of bovine respiratory disease in stocker cattle. *Vet Ther* 2005; 6(2): 167-179.

³ Rooney KA, Nutsch RG, Skogerboe TL, Weigel DJ, Gajewski K, Kilgore WR. Efficacy of tulathromycin compared with tilmicosin and florfenicol for the control of respiratory disease in cattle at high risk of developing bovine respiratory disease. *Vet Ther* 2005; 6(2): 154-166.

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NEW
DraxxinTM
 (tulathromycin)
 Injectable Solution



**The single-dose convenience you want.
 The effectiveness you need.TM**



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See page 301 for Product Information Summary.