PRODUCT PROFILE

Tenotryl™ (enrofloxacin) injectable solution

Product Description

- Tenotryl (enrofloxacin) injectable solution possesses the activity needed to kill most of the primary SRD pathogens and *E. coli.*
- Enrofloxacin is a broad-spectrum antibiotic with low minimal inhibitory concentration (MIC) on the primary agents of SRD and colibacillosis associated with *E. coli.* Its bactericidal effects are concentration or time dependent.[1]

Indication

- Tenotryl injectable solution is indicated for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae.*
- It is also indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed. To assure responsible antimicrobial drug use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options.

Dosage / Administration

- **(SRD Treatment):** Administer, by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lbs.). Administered dose volume should not exceed 5 mL per injection site.
- **(Colibacillosis Control):** Initiate administration within the first 60 days post-weaning when clinical signs are present in at least 2% of animals in the group. Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lbs.). Administered dose volume should not exceed 5 mL per injection site.

Formulation

- Tenotryl injectable solution contains 100 mg enrofloxacin / mL, an injectable solution for intramuscular or subcutaneous (behind the ear) injection use in swine.*

Precautions

(see back label for list of precautions)

- The effects of enrofloxacin on swine reproductive performance, pregnancy and lactation have not been adequately determined.
- The long-term effects on articular joint cartilage have not been determined in pigs above market weight.
- Subcutaneous injection or intramuscular injection in swine can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.
- U.S. federal law restricts this drug to use by or on the order of a licensed veterinarian and prohibits the extra-label use of this drug in food-producing animals.

Withdrawal Period

- Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

Key Features

- Enrofloxacin, the active ingredient in Tenotryl (enrofloxacin) injectable solution is an efficient, broad-spectrum antibiotic that has been trusted in the U.S. swine industry for 25 years.
- A convenient, single-dose injection delivers swift and broad action against seven bacterial pathogens that cause swine respiratory disease (SRD), as well as colibacillosis associated with *E. coli.*

SWINE IMPORTANT SAFETY INFORMATION

Tenotryl (enrofloxacin) 100 mg/ml Antimicrobial Injectable Solution: Animals intended for human consumption must not be slaughtered within 5 days of receiving a single injection dose. To assure responsible antimicrobial drug use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options. Federal (USA) law prohibits the extra-label use of this drug in food producing animals.

*Also approved for use in beef and non-lactating diary cattle. For more information, contact your Pharmgate representative.

The labeling contains complete use information, including cautions and warnings. Always read, understand and follow the labeling and use directions. See the back page for use directions and additional information.

Pharmgate ANIMAL HEALTH

Brief Summary of Prescribing Info for Swine

Tenotryl™ (enrofloxacin) 100 mg/mL Antimicrobial Injectable Solution

For Intramuscular Or Subcutaneous Use In Swine

CAUTION:
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Federal (USA) law prohibits the extra-label use of this drug in food-producing animals. To assure responsible antimicrobial drug use, enrofloxacin should only be used as a second-line drug for colibacillosis in swine following consideration of other therapeutic options.

INDICATIONS:
Tenotryl™ is indicated for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*. Tenotryl™ is indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

DOSAGE AND ADMINISTRATION:
Tenotryl™ provides flexible dosages and durations of therapy. Tenotryl™ may be administered for treatment and control of SRD or for control of colibacillosis. Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb). Administered dose volume should not exceed 5 mL per injection site. For the control of colibacillosis, administration should be initiated within the first 60 days post-weaning when clinical signs are present in at least 2% of animals in the group. If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

Table 1 – Dose Schedule for Swine

Weight (lb)	Dose Volume (mL)
15	0.5
30	1.0
50	1.7
100	3.4
150	5.1
200	6.8
250	8.5

Dilution of Tenotryl: Tenotryl™ may be diluted with sterile water prior to injection. The diluted product should be used within 24 hours. Store diluted solution in amber glass bottles between 5°C - 40°C (41°F - 104°F), excursions are not permitted.

Table 2 – Dilution Schedule*

Swine Weight	mL of Tenotryl™	mL of sterile water	Number of doses
10 lb	34 mL	66 mL	100
15 lb	51 mL	49 mL	100
20 lb	68 mL	32 mL	100
25 lb	85 mL	15 mL	100

*For 1 mL dose volume from diluted solution

Use within 30 days of first puncture and puncture a maximum of 30 times with a 16-gauge needle or smaller, or 4 times with a draw-off spike 4.75 mm or smaller. Any product remaining beyond these parameters should be discarded.

RESIDUE WARNINGS:
Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

HUMAN WARNINGS:
Not for use in humans. Keep out of reach of children.

PRECAUTIONS:
The effects of enrofloxacin on swine reproductive performance, pregnancy and lactation have not been adequately determined.
The long-term effects on articular joint cartilage have not been determined in pigs above market weight.
Subcutaneous injection or intramuscular injection in swine can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.
Enrofloxacin injectable solution contains different excipients than other enrofloxacin products. The safety and efficacy of this formulation in species other than cattle and swine have not been determined.
Quinolone-class drugs should be used with caution in animals with known or suspected Central Nervous System (CNS) disorders. In such animals, quinolones have, in rare cases, been associated with CNS stimulation which may lead to convulsive seizures.
Quinolone-class drugs have been shown to produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species.
See Animal Safety Section in the full prescribing information for additional details.

ADVERSE REACTIONS:
No adverse reactions were observed during clinical trials.
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, call 1-800-338-3659.
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

STORAGE CONDITIONS:
Protect from direct sunlight. Do not refrigerate or freeze.
Store at 20-30°C (68-86°F), excursions permitted between 15°C (59°F) to 40°C (104°F). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

HOW SUPPLIED:
Tenotryl™ (enrofloxacin) Injectable Solution:

100 mg/mL	100 mL Bottle
100 mg/mL	250 mL Bottle
100 mg/mL	500 mL Bottle

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Rev. 12/21

Approved by FDA under ANADA # 200-688
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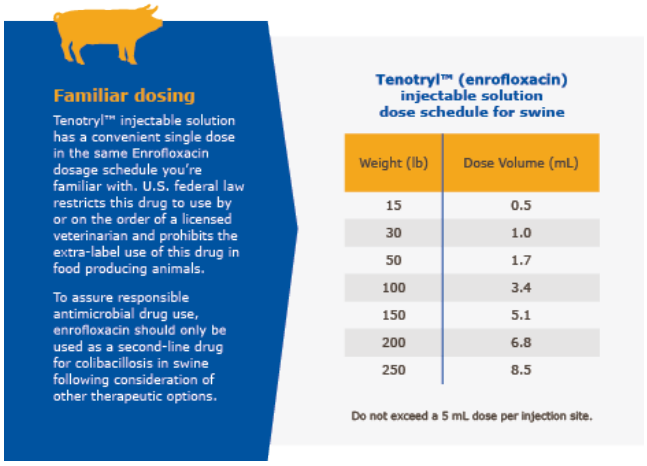

Packaging

- 100 mL vials, 20 bottles/case
- 250 mL vials, 15 bottles/case
- 500 mL vials, 6 boxes/case

Storage

- Protect from direct sunlight. Do not refrigerate or freeze. Store at 20-30°C (68-86°F), excursions permitted between 15°C (59°F) to 40°C (104°F). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.
- Use within 30 days of first puncture and puncture a maximum of 30 times with a 16-gauge needle or smaller, or 4 times with a draw-off spike 4.75 mm or smaller. Any product remaining beyond these parameters should be discarded.

[1] Giguére, S.; Prescot, J.F.; Dowling, P.M. 2013. *Antimicrobial Therapy in Veterinary Medicine, Fifth Edition.*

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Consult the full prescribing information for complete use information, including cautions and warnings. Always read, understand and follow the labeling and use directions. See label for the full prescribing information.

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