

Date of Approval: JUN 21 2005

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-360

Tiamulin Liquid Concentrate
(12.3% tiamulin hydrogen fumarate)

Swine

For oral use in the treatment of swine dysentery and pneumonia

Sponsored by:

Phoenix Scientific, Inc.

2005-200-360

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-360
- b. Sponsor: Phoenix Scientific, Inc.
3915 South 48th Street Ter.
St. Joseph, MO 64503

Drug Labeler Code: 059130
- c. Established Names: Tiamulin hydrogen fumarate
- d. Proprietary Name: Tiamulin Liquid Concentrate
- e. Dosage Form: Liquid
- f. How Supplied: 32 fl oz bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 12.3% tiamulin hydrogen fumarate
- i. Route of Administration: Oral
- j. Species/Class: Swine/Weighing less than 250 pounds.
- k. Recommended Dosage: Administered in the drinking water for five consecutive days for the treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.
- l. Pharmacological Category: Antibiotic
- m. Indications: For the treatment of swine dysentery associated with *Brachyspira hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.
- n. Pioneer Product: DENAGARD Liquid Concentrate; tiamulin; NADA 140-916; Boehringer Ingelheim Vetmedica, Inc.

2. **TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for Tiamulin (tiamulin hydrogen fumarate) Liquid Concentrate. The generic product is administered as an oral solution, contains similar active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product DENAGARD (tiamulin hydrogen fumarate) Liquid Concentrate, the subject of Boehringer Ingelheim Vetmedica, Inc., NADA 140-916, was approved on January 29 1993.

3. **HUMAN SAFETY:**

- **Tolerance for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.6 ppm is established for 8-*alpha*-hydroxymutilin (marker compound) in liver (target tissue) of swine under 21 CFR 556.738.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times established for tiamulin liquid concentrate under 21 CFR 520.2456 are: 1) 3 days before slaughter when given to swine at a dose of 3.5 mg of tiamulin per pound of body weight for 5 days, and 2) 7 days before slaughter when given to swine at a dose of 10.5 mg per pound of body weight for 5 days.

- **Regulatory Method for Residues:**

The determinative analytical method (GC) and the confirmatory analytical method (GC-MS) for determining 8-*alpha*-hydroxymutilin in swine liver are on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Tiamulin Liquid Concentrate, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-360:

Tiamulin (tiamulin) Liquid Concentrate
Container Label – one quart (32 fl oz; 946 mL)
Package Insert

Pioneer Labeling for NADA 140-916:

DENAGARD (tiamulin) Liquid Concentrate
Container Label – one quart (32 fl oz; 946 mL)
Package Insert

Warning: Keep out of reach of children. Avoid direct contact with the skin. Direct contact with skin or mucous membranes may cause irritation.

Withdraw medicated water 3 days before slaughter after use at 3.5 mg per pound and 7 days before slaughter after use at 10.5 mg per pound.

Active Ingredient: This bottle contains 4.10 oz (116.4 g) tiamulin hydrogen fumarate in solution.

Caution: For use in animals only - Not for human use.

Prepare fresh medicated water daily. Use as the only source of drinking water for 5 days. Do not use in swine weighing over 250 pounds.

Store at controlled room temperature 20°-25°C (68°-77°F)

AmTech® is a registered trademark of Phoenix Scientific, Inc.



TAKE TIME



OBSERVE LABEL DIRECTIONS

Lot No.

Exp. Date

NDC 59130-753-18

Tiamulin Liquid Concentrate

12.3% tiamulin
hydrogen fumarate

ANTIBOTIC

ANADA 200-360, Approved by FDA

NET CONTENTS:

1 Quart (32 fl oz; 946 mL)

AmTech®
Group, Inc.

Contraindications: Swine being treated with Tiamulin Liquid Concentrate should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.

Indications: Treatment of swine dysentery associated with *Brachyspira hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae*, susceptible to tiamulin.

Use Directions: SHAKE WELL BEFORE USING. Do not use undiluted.

This bottle contains 116,400 mg tiamulin hydrogen fumarate for use in preparing medicated drinking water for swine. See package insert for complete directions, read completely.

Protect from direct sunlight

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

500028

Iss. 4-05



Contraindications: Swine being treated with Tiamulin Liquid Concentrate should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.

Indications: Treatment of swine dysentery associated with *Brachyspira hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae*, susceptible to tiamulin.

Use Directions: SHAKE WELL BEFORE USING. Do not use undiluted.

This bottle contains 116,400 mg tiamulin hydrogen fumarate for use in preparing medicated drinking water for swine. See package insert for complete directions, read completely.

Protect from direct sunlight

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

500028

Iss. 4-05

ANADA 200-360, Approved by FDA

Tiamulin Liquid Concentrate

Description: Tiamulin Liquid Concentrate is a solution containing 12.3% tiamulin hydrogen fumarate (w/v) in an aqueous solution. The active ingredient, tiamulin, chemically is 14-desoxy-14-[(2-diethylaminoethyl) mercaptoacetoxy] mutilin hydrogen fumarate, a semi-synthetic diterpene antibiotic. Tiamulin Liquid Concentrate is for use only in preparing medicated drinking water for swine.

Actions: Tiamulin is active against *Brachyspira hyodysenteriae* and *Actinobacillus pleuropneumoniae*. It is readily absorbed from the gut and can be found in the blood within 30 minutes after dosing.

Indications: Tiamulin Liquid Concentrate, when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

Contraindications: Swine being treated with Tiamulin Liquid Concentrate should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.

Warning: Keep out of reach of children. Avoid contact with skin. Direct contact with skin or mucous membranes may cause irritation.

Withdraw medicated water 3 days before slaughter after treatment at 3.5 mg per pound and 7 days before slaughter following treatment at 10.5 mg per pound body weight.

Caution: For use in drinking water of swine only. Prepare fresh medicated water daily. Not for use in

swine over 250 pounds body weight. For animal use only - not for use in humans.

Adverse reactions: Overdoses of Tiamulin Liquid Concentrate have sometimes produced transitory salivation, vomiting and an apparent calming effect on the pig. If signs of toxicity occur, discontinue use of medicated water and replace with clean, fresh water. In rare cases, redness of the skin primarily over the hams and underline has been observed during medication. If these signs appear, discontinue use of this drug. Provide ample clean drinking water. Thoroughly rinse (hose down) the housing to remove urine and feces from animal contact surfaces or move the animals to clean pens. If the condition persists, consult your veterinarian.

Studies to evaluate the safety of the water soluble form of tiamulin in breeding swine have not been done.

Use Directions: The concentration of tiamulin in the drinking water must be adjusted to compensate for variation in water consumption due to weight or size of the pig, environmental temperature and other factors. It is important that pigs receive the proper drug dose, 3.5 mg tiamulin hydrogen fumarate per pound for swine dysentery or 10.5 mg tiamulin hydrogen fumarate per pound for swine pneumonia, each day for 5 consecutive days.

Table 1

Approximate daily water consumption per pig.

Pig Weight, lb	Water Intake, gal.	Pig Weight, lb	Water Intake, gal.
20	0.3-0.5	125	1.0-2.0
45	0.4-1.1	180	1.2-3.0
75	0.7-1.5		

Notes:

1. Prepare fresh medicated drinking water every day for the 5 day treatment period.
2. Water medicated with Tiamulin Liquid Concentrate should be the only source of drinking water during the treatment period.

Directions for preparing Tiamulin Liquid Concentrate medicated solutions:

SHAKE WELL BEFORE USING. Determine the amount of Tiamulin Liquid Concentrate needed to medicate the desired volume of drinking water at the proper concentration. Carefully measure out this amount, add it to the water and stir thoroughly mix.

Table 2 Tiamulin Liquid Concentrate

One Quart			
Net Tiamulin hydrogen fumarate Content:		116,400 mg	
Diseases to be treated:	Swine Dysentery	Swine Pneumonia	
Daily tiamulin hydrogen fumarate required per pound body weight:	3.5 mg	10.5 mg	
Required treatment duration:	5 days	5 days	
Pig body weight this bottle will treat for ONE day:	33,257 lb	11,086 lb	
Number of pigs this bottle will treat for ONE day:	Pig Wt., lb		
	20	1,663	554
	45	739	246
	75	443	148
	125	266	88
	180	185	62
Suggested final dilution of:		512 gal	
1 quart (32 fl oz)			512 gal
3 quarts (96 fl oz)		128 gal	43 gal
1/2 pint (8 fl oz)			128 gal
1 1/2 pints (24 fl oz)			
Tiamulin hydrogen fumarate concentration per gallon at suggested final dilution*	227 mg (60 ppm)	681 mg (180 ppm)	

*Note: Increase or decrease dilution rate as required to obtain proper daily drug dose.

Directions for using Tiamulin Liquid Concentrate in medicated proportioners: One quart of Tiamulin Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide

227 mg tiamulin hydrogen fumarate per gallon to 512 gallons of drinking water for treatment of swine dysentery. Three quarts of Tiamulin Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide 681 mg tiamulin hydrogen fumarate per gallon to a total of 512 gallons of drinking water for treatment of swine pneumonia.

One pint of Tiamulin Liquid Concentrate mixed with water to make two gallons of stock solution and this stock solution metered at one fluid ounce per gallon will provide 227 mg of tiamulin hydrogen fumarate per gallon to 256 gallons of drinking water for treatment of swine dysentery. Use three pints of Tiamulin Liquid Concentrate in two gallons of stock solution to be metered at one fluid ounce per gallon to deliver 681 mg per gallon to a total of 256 gallons of drinking water for treatment of swine pneumonia.

One-half pint (8 fluid ounces) of Tiamulin Liquid Concentrate diluted with water to make one gallon of stock solution and this solution metered at one fluid ounce of drinking water with a medication proportioner will provide 227 mg of tiamulin hydrogen fumarate per gallon to 128 gallons of drinking water for treatment of swine dysentery. Use one and one-half pints of Tiamulin Liquid Concentrate per gallon of stock solution to be metered at one fluid ounce per gallon to provide 681 mg per gallon to 128 gallons of drinking water for treatment of swine pneumonia.

In barrels or tanks: Three fluid ounces of Tiamulin Liquid Concentrate will medicate 48 gallons of drinking water at 227 mg per gallon for treatment of swine dysentery or 16 gallons at 681 mg per gallon for treatment of swine pneumonia. Measure Tiamulin Liquid Concentrate carefully, pour into the proper amount of water and thoroughly mix. The concentration of tiamulin hydrogen fumarate in the stock solution and in the drinking water delivered must be adjusted to compensate for variation in water consumption by pigs due to body weight, environmental and other

factors. It is important that the pigs receive the proper drug dose of 3.5 mg of tiamulin hydrogen fumarate per pound of body weight daily for 5 consecutive days for treatment of swine dysentery or a dose of 10.5 mg per pound body weight daily for 5 consecutive days for treatment of swine pneumonia.

Attention: If no response to treatment is obtained within 5 days re-establish the diagnosis. Failure of response may be related to the presence of non-susceptible organisms of other complicating disease conditions. Because of the tendency for the disease to recur on premises with a history of swine dysentery or with swine pneumonia, a control program should be implemented after treatment. Drugs are not substitutes for proper sanitary measures or good management, but should be used in conjunction with such practices.

How supplied:

Container Size	Active Ingredients
Quart bottles (32 fl oz; 946 mL)	12.3% (116.4g) Tiamulin hydrogen fumarate

Protect from direct sunlight. Observe expiration date.

Store at controlled room temperature 20°-25°C (68°-77°F)

AmTech® is a registered trademark of Phoenix Scientific, Inc.

NADA 140-916, Approved by FDA

Denagard™ (tiamulin)

Liquid Concentrate

Description: Denagard (tiamulin) Liquid Concentrate is a solution containing 22.2% tiamulin hydrogen fumarate (w/v) in an aqueous solution. The active ingredient, tiamulin, chemically is 4-(2-oxo-1,2-dihydroquinolin-3-yl)pyrrolidine-2-carboxamide, tiamulin hydrogen fumarate, a semi-synthetic dihydroquinoline. Denagard Liquid Concentrate is for use only in preparing medicated drinking water for swine. **Action:** Tiamulin is active against *Streptococcus* (formerly *Streptococcus* and *Streptococcus*) and *Actinobacillus pleuropneumoniae*. It is readily absorbed from the gut and can be found in the blood within 30 minutes after dosing.

Indications: Denagard (tiamulin), when administered in the drinking water for five consecutive days, is an effective antibiotic for the treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*).

Precautions: Use Denagard (tiamulin) at a dose level of 3.5 mg tiamulin hydrogen fumarate per pound of body weight daily and for treatment of swine pleuropneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin when given at 10.5 mg tiamulin hydrogen fumarate per pound of body weight daily.

Contraindications: Swine being treated with Denagard (tiamulin) should not have access to feeds containing copper sulphate or (e.g., molybdenum, iron, zinc, selenium and vitamins) as adverse reactions may occur.

Warnings: Keep out of reach of children. Avoid contact with skin. Direct contact with skin or mucous membranes may cause irritation. Withdraw medicated water 3 days before slaughter after treatment at 2.5 mg per pound and 7 days before slaughter following treatment at 10.5 mg per pound body weight. Caution: For use in drinking water of swine only. Prepare fresh medicated water daily. Not for use in swine over 250 pounds body weight. For animal use only—do not use in humans.

Adverse Reactions: Directions of Denagard show sometimes transient respiratory irritation, sneezing and an apparent calming effect on the pig. If signs of toxicity occur, discontinue use of medicated water and replace with clean, fresh water. In rare cases, redness of the skin primarily over the hams and underlines has been observed during medication. If these signs appear, discontinue use of this drug. Provide ample shade to remove urine and feces from animal contact surfaces or move the animals to clean pens. If the condition persists, consult your veterinarian.

Studies to evaluate the safety of the water soluble form of tiamulin in breeding swine have not been done. **Use Directions:** The concentration of tiamulin in the drinking water must be adjusted to compensate for variation in water consumption due to weight or size of the pig, environmental temperature and other factors. It is important that pigs receive the proper drug dose. 3.5 mg tiamulin hydrogen fumarate per pound for swine dysentery or 10.5 mg tiamulin hydrogen fumarate per pound for swine pleuropneumonia, each day for 5 consecutive days.

Table 1
Approximate daily water consumption per pig.

Pig Weight, lb.	Water Intake, gal.	Pig Weight, lb.	Water Intake, gal.
50	0.1-0.3	175	1.0-2.0
55	0.1-1.1	180	1.2-3.0
75	0.7-1.8		

Note:

1. Prepare fresh medicated drinking water every day for the 5 day treatment period.
2. Water medicated with Denagard should be the only source of drinking water during the treatment period.

Directions for preparing Denagard medicated solutions:

Determine the amount of Denagard Liquid Concentrate needed to medicate the desired volume of drinking water at the proper concentration. Carefully measure out this amount, add it to the water and stir thoroughly.

Table 2 Denagard Liquid Concentrate

Denagard Liquid Concentrate	One Quart (946.35 ml) 10.468% Tiamulin	One Gallon (128 fl. oz.) 12.562% Tiamulin
Net Tiamulin Hydrogen Fumarate Content:		
Denagard Liquid Concentrate	3.5 mg	10.5 mg
100% tiamulin hydrogen fumarate received per pound body weight	0.08 mg	0.24 mg
Tiamulin Hydrogen Fumarate Content:		
Pig Body Weight, lbs. 100 lb.	\$2.277 lb.	11.288 lb.
150 lb.		
200 lb.		
250 lb.		
300 lb.		
350 lb.		
400 lb.		
450 lb.		
500 lb.		
550 lb.		
600 lb.		
650 lb.		
700 lb.		
750 lb.		
800 lb.		
850 lb.		
900 lb.		
950 lb.		
1000 lb.		
1050 lb.		
1100 lb.		
1150 lb.		
1200 lb.		
1250 lb.		
1300 lb.		
1350 lb.		
1400 lb.		
1450 lb.		
1500 lb.		
1550 lb.		
1600 lb.		
1650 lb.		
1700 lb.		
1750 lb.		
1800 lb.		
1850 lb.		
1900 lb.		
1950 lb.		
2000 lb.		
2050 lb.		
2100 lb.		
2150 lb.		
2200 lb.		
2250 lb.		
2300 lb.		
2350 lb.		
2400 lb.		
2450 lb.		
2500 lb.		
2550 lb.		
2600 lb.		
2650 lb.		
2700 lb.		
2750 lb.		
2800 lb.		
2850 lb.		
2900 lb.		
2950 lb.		
3000 lb.		
3050 lb.		
3100 lb.		
3150 lb.		
3200 lb.		
3250 lb.		
3300 lb.		
3350 lb.		
3400 lb.		
3450 lb.		
3500 lb.		
3550 lb.		
3600 lb.		
3650 lb.		
3700 lb.		
3750 lb.		
3800 lb.		
3850 lb.		
3900 lb.		
3950 lb.		
4000 lb.		
4050 lb.		
4100 lb.		
4150 lb.		
4200 lb.		
4250 lb.		
4300 lb.		
4350 lb.		
4400 lb.		
4450 lb.		
4500 lb.		
4550 lb.		
4600 lb.		
4650 lb.		
4700 lb.		
4750 lb.		
4800 lb.		
4850 lb.		
4900 lb.		
4950 lb.		
5000 lb.		
5050 lb.		
5100 lb.		
5150 lb.		
5200 lb.		
5250 lb.		
5300 lb.		
5350 lb.		
5400 lb.		
5450 lb.		
5500 lb.		
5550 lb.		
5600 lb.		
5650 lb.		
5700 lb.		
5750 lb.		
5800 lb.		
5850 lb.		
5900 lb.		
5950 lb.		
6000 lb.		
6050 lb.		
6100 lb.		
6150 lb.		
6200 lb.		
6250 lb.		
6300 lb.		
6350 lb.		
6400 lb.		
6450 lb.		
6500 lb.		
6550 lb.		
6600 lb.		
6650 lb.		
6700 lb.		
6750 lb.		
6800 lb.		
6850 lb.		
6900 lb.		
6950 lb.		
7000 lb.		
7050 lb.		
7100 lb.		
7150 lb.		
7200 lb.		
7250 lb.		
7300 lb.		
7350 lb.		
7400 lb.		
7450 lb.		
7500 lb.		
7550 lb.		
7600 lb.		
7650 lb.		
7700 lb.		
7750 lb.		
7800 lb.		
7850 lb.		
7900 lb.		
7950 lb.		
8000 lb.		
8050 lb.		
8100 lb.		
8150 lb.		
8200 lb.		
8250 lb.		
8300 lb.		
8350 lb.		
8400 lb.		
8450 lb.		
8500 lb.		
8550 lb.		
8600 lb.		
8650 lb.		
8700 lb.		
8750 lb.		
8800 lb.		
8850 lb.		
8900 lb.		
8950 lb.		
9000 lb.		
9050 lb.		
9100 lb.		
9150 lb.		
9200 lb.		
9250 lb.		
9300 lb.		
9350 lb.		
9400 lb.		
9450 lb.		
9500 lb.		
9550 lb.		
9600 lb.		
9650 lb.		
9700 lb.		
9750 lb.		
9800 lb.		
9850 lb.		
9900 lb.		
9950 lb.		
10000 lb.		

*Water intake or consumption data are based on average values from 1970-1975.

Directions for using Denagard

In medicated preparations: One quart of Denagard Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution mixed at one fluid ounce per gallon will provide 227 mg of tiamulin hydrogen fumarate per gallon of drinking water for treatment of swine dysentery. Three quarts of Denagard Liquid Concentrate mixed with water to make four gallons of stock solution and this stock solution mixed at one fluid ounce per gallon will provide 681 mg tiamulin hydrogen fumarate per gallon for treatment of swine pleuropneumonia.

One pint of Denagard Liquid Concentrate mixed with water to make two gallons of stock solution and this stock solution mixed at one fluid ounce per gallon will provide 297 mg of tiamulin hydrogen fumarate per gallon of drinking water for treatment of swine dysentery. Use three pints of Denagard Liquid Concentrate in two gallons of stock solution to be mixed at one fluid ounce per gallon to deliver 891 mg per gallon to a total of 256 gallons of drinking water for treatment of swine pleuropneumonia.

One-half pint (8 fluid ounces) of Denagard Liquid Concentrate diluted with water to make one gallon of stock solution and this stock solution mixed at one fluid ounce of drinking water will provide 227 mg of tiamulin hydrogen fumarate per gallon to 228 gallons of drinking water for treatment of swine dysentery. Use one and one-half pints of Denagard Liquid Concentrate per gallon of stock solution to be mixed

at one fluid ounce per gallon to provide 681 mg per gallon to 128 gallons of drinking water for treatment of swine pleuropneumonia.

In barrels or tanks: Three fluid ounces of Denagard Liquid Concentrate will medicate 40 gallons of drinking water at 227 mg per gallon for treatment of swine dysentery or 681 mg per gallon for treatment of swine pleuropneumonia.

Mix Denagard Liquid Concentrate carefully, pour into the proper amount of water and thoroughly mix. The concentration of tiamulin hydrogen fumarate in the stock solution used in the drinking water delivered must be adjusted to compensate for variation in water consumption by pigs due to body weight, environmental and other factors. It is important that the pigs receive the proper drug dose of 3.5 mg of tiamulin hydrogen fumarate per pound of body weight daily for 5 consecutive days for treatment of swine dysentery.

Use three pints of Denagard Liquid Concentrate in two gallons of stock solution to be mixed at one fluid ounce per gallon to deliver 891 mg per gallon to a total of 256 gallons of drinking water for treatment of swine pleuropneumonia. If no response to treatment is obtained within 5 days re-evaluate the diagnosis. Failure of response may be related to the presence of non-susceptible organisms of other complicating disease conditions. Because of the tendency for disease to recur, all patients with a history of swine dysentery or with swine pleuropneumonia, clinical progress should be kept under close observation. Drugs are not substitutes for proper sanitary measures or good management, but should be used in conjunction with such practices.