

DENAGARD- tiamulin fumarate concentrate
Elanco US Inc.

Denagard™ 12.5%
(tiamulin hydrogen fumarate)

Liquid Concentrate

Description:

Denagard (tiamulin) Liquid Concentrate is a solution containing 12.5 % 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. Denagard Liquid Concentrate is for use only in preparing medicated drinking water for swine.

Actions:

Tiamulin is active against *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* 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*) *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 Denagard (tiamulin) 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.

Residue Warnings:

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. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined.

For animal use only – not for use in humans.

Adverse Reactions:

Overdoses of Denagard 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 ham 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.

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 to thoroughly mix.

Number of pigs this bottle will treat for ONE day based on water consumption per pig		One Liter	
Net tiamulin hydrogen fumarate content:		125,000 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 Wt, lb	Water Intake, gal	# of Pigs	# of Pigs
20	0.3 - 0.5	1,786	595

45	0.4 - 1.1	794	265
75	0.7 - 1.5	476	159
125	1.0 - 2.0	286	95
180	1.2 - 3.0	198	66
Suggested final dilution of:	1 bottle (1 Liter)	550 gal	183 gal
	3 bottles (3 Liters)	1650 gal	550 gal
	1/2 bottle (0.5 Liters)	275 gal	92 gal
Tiamulin hydrogen fumarate concentration per gallon at suggested final dilution*		227 mg (60 ppm)	681 mg (180 ppm)

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.

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

Directions for using Denagard

In medicated proportioners: One liter of Denagard Liquid Concentrate mixed with water to make 4.3 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 550 gallons of drinking water for treatment of swine dysentery.

Three liters of Denagard Liquid Concentrate mixed with water to make 4.3 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 550 gallons of drinking water for treatment of swine pneumonia.

In barrels or tanks: One liter (1000 mL) of Denagard Liquid Concentrate will medicate 550 gallons of drinking water at 227 mg per gallon for treatment of swine dysentery or 183 gallons at 681 mg per gallon for treatment of swine pneumonia at 381 mg per gallon for treatment of swine pneumonia.

Measure Denagard 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
1 Liter bottle (33.8 fl oz; 1000 mL)	12.5% (125.0 g) Tiamulin hydrogen fumarate
5 Liter bottle (169 fl oz; 5000 mL)	12.5% (625.0 g) Tiamulin hydrogen fumarate
Protect from direct sunlight. Store at controlled room temperature, 59 °–77 °F (15 °–25 °C).	

Observe expiration date.

**For technical assistance,
call Elanco US Inc.
at 1-800-428-4441**

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Elanco™

Principal Display Panel - Denagard 1000 mL Bottle Label

Dengard™ 12.5%

(tiamulin hydrogen fumarate)

12.5% Tiamulin hydrogen fumarate

NADA 140-916, Approved by FDA

One Liter (1.057 Quarts)

(33.8 fl oz; 1000 mL)

Denagard™ 12.5%

(tiamulin hydrogen fumarate)



Liquid Concentrate

12.5% Tiamulin hydrogen fumarate

NADA 140-916, Approved by FDA

One Liter (1.057 Quarts)
(33.8 fl oz; 1000 mL)

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

Residue Warnings: 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 4.33 oz (125.0 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. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined.

Contraindication: Swine being treated with Denagard (tiamulin) 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* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* and swine pneumonia due to *Actinobacillus pleuropneumoniae*, susceptible to tiamulin.

Use Directions: Do not use undiluted.

This bottle contains 125,000 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. Store at controlled room temperature, 59°–77°F (15°–25°C).

Restricted Drug (California): Use only as directed

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Product 607728

Manufactured for: Elanco US Inc.
Greenfield, IN 46140, USA



GTIN: (01)

Lot No.:

Exp. :



YL100139AMX 311546

Principal Display Panel - Denagard 5000 mL Bottle Label

Denagard™ 12.5%

(tiamulin hydrogen fumarate)

12.5% Tiamulin hydrogen fumarate

NADA 140-916, Approved by FDA

Five Liter (5.285 Quarts)

(169 fl oz; 5000 mL)

Denagard™ 12.5%

(tiamulin hydrogen fumarate)



5L Liquid
Concentrate

12.5% Tiamulin hydrogen fumarate

NADA 140-916, Approved by FDA

Five Liter (5.285 Quarts)

(169 fl oz; 5000 mL)

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

Residue Warnings: 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 21.65 oz (625.0 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. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined.

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

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*) *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.

Use Directions: Do not use undiluted. This bottle contains 625,000 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. Store at controlled room temperature, 59°–77°F (15°–25°C).

Restricted Drug (California): Use only as directed

Description: Denagard (tiamulin) Liquid Concentrate is a solution containing 12.5% tiamulin hydrogen fumarate (w/v) in an aqueous solution. The active ingredient, tiamulin hydrogen fumarate, chemically is 14-desoxy-14-[(2-diethylaminoethyl) mercaptoacetoxyl] mutilin hydrogen fumarate, a semi-synthetic diterpene antibiotic. Denagard Liquid Concentrate is for use only in preparing medicated drinking water for swine.

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

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Manufactured for: Elanco US Inc.
Greenfield, IN 46140, USA



YL100140AMA 311545

DENAGARD

tiamulin fumarate concentrate

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58198-7425
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
tiamulin fumarate (UNII: ION1Q02ZCX) (TIAMULIN - UNII:E38WZ4U54R)	tiamulin fumarate	0.125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-7425-1	1000 mL in 1 BOTTLE		
2	NDC:58198-7425-2	5000 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA		NADA140916	06/14/2010	

Labeler - Elanco US Inc. (966985624)