

DENAGARD- tiamulin fumarate solution, concentrate
Novartis Animal Health US, Inc.

Denagard-Liquid Concentrate

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)

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 **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 3.5mg 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 10.5mg 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) 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.

Denagard® is a registered trademark of Novartis AG
Product 610467
NAH/DEN-LC/12.5/BLF-5L/2

**Manufactured for: Novartis Animal Health US, Inc.
Greensboro, NC 27408 U.S.A.**

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, 3.5mg tiamulin hydrogen fumarate per pound for swine dysentery or 10.5mg 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**

Five Liters

Net tiamulin hydrogen fumarate content:	625,000 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	8,930	2,975
45	0.4 – 1.1	3,970	1,325
75	0.7 – 1.5	2,380	795
125	1.0 – 2.0	1,430	475
180	1.2 – 3.0	990	330
Suggested final dilution of:	1 bottle (5 Liters)	2750 gal	917 gal
	3 bottles (15 Liters)	8250 gal	2750 gal
	½ bottle (2.5 Liters)	1375 gal	458 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:

Five liters of Denagard Liquid Concentrate mixed with water to make 21.5 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 2750 gallons of drinking water for treatment of swine dysentery. Fifteen liters of Denagard Liquid Concentrate mixed with water to make 21.5 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 2750 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.

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 3.5mg of tiamulin hydrogen fumarate per pound of body weight daily for 5 consecutive days for treatment of swine dysentery or a dose of 10.5mg 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 or 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 bottles (33.8 fl oz; 1000 mL)	12.5% (125.0 g) Tiamulin hydrogen fumarate
5 Liter bottle (169 fl oz; 5000 mL)	12.5% (125.0 g) Tiamulin hydrogen fumarate

Observe expiration date.

**For technical assistance, call Novartis Animal Health
US Inc. at 1-800-843-3386.**

Principal Display Panel

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NADA 140-916,
Approved by FDA
Five Liter (5.285 Quarts)
(169 fl oz; 5000 mL)**

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(tiamulin hydrogen fumarate)



5L Liquid Concentrate

12.5% Tiamulin hydrogen fumarate

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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.

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Manufactured for: Novartis Animal Health US, Inc.
Greensboro, NC 27408 U.S.A.

614290 a/USA 311545

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NOVARTIS
ANIMAL HEALTH

DENAGARD

tiamulin solution, concentrate

Product Information

Product Type	OTC ANIMAL DRUG LABEL	Item Code (Source)	NDC:58 198-7728
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TIAMULIN FUMARATE (TIAMULIN)	TIAMULIN FUMARATE	0.125 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:58 198-7728-1	1000 mL in 1 BOTTLE		
2	NDC:58 198-7728-2	5000 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140916	06/14/2010	

Labeler - Novartis Animal Health US, Inc. (966985624)

Establishment

Name	Address	ID/FEI	Business Operations
Sandoz Industrial Products S.p.A		429636954	API MANUFACTURE

Revised: 4/2014

Novartis Animal Health US, Inc.