TiaGard® 12.5%

(Tiamulin hydrogen fumarate)

Liquid Concentrate 12.5% Tiamulin hydrogen fumarate

Approved by FDA under ANADA # 200-717 One Liter (1.057 Quarts) (33.8 fl. oz; 1000 mL)

Five Liter (5.285 Quarts) (169 fl. oz; 5000 mL)

Directions for using TiaGard 12.5%

In medicated proportioners:

One liter of TiaGard 12.5% 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 TiaGard 12.5% 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

Five liters of TiaGard 12.5% 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 TiaGard 12.5% 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.

One liter (1000 mL) of TiaGard 12.5% 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 TiaGard 12.5% 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.

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.

Container Size	Active Ingredients
1 Liter bottles	12.5% (125.0 g)
(33.8 fl oz; 1000 mL)	Tiamulin hydrogen fumarate
5 Liter bottles	12.5% (625.0 g)
(169 fl oz; 5000 mL)	Tiamulin hydrogen fumarate

Protect from direct sunlight. Store upright at controlled temperature, 59°-77°F (15°-25°C). Use stock solutions within 24 hours after preparation. Do not store stock or diluted solutions in

Observe expiration date.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Aurora Pharmaceutical at 1-888-215-1256 or http://www.aurorapharmaceutical.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Description:

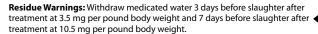
TiaGard 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate is a solution containing 12.5% tiamulin hydrogen fumarate (w/v) in an aqueous solution. The active ingredient, tiamulin hydrogen fumarate, chemically is 14-desoxy-14-[(2-diethylaminoethyl) mercaptoacetoxyl] mutilin hydrogen fumarate, a semi-synthetic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

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: TiaGard 12.5% (tiamulin hydrogen fumarate), 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 TiaGard 12.5% (tiamulin hydrogen fumarate) should not have access to feeds containing polyether ionophores (e.g., monensing 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.



Caution: For use in drinking water of swine only — Not for use in humans.

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

Adverse Reactions:

Overdoses of tiamulin hydrogen fumarate 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

Use Directions:

The concentration of tiamulin hydrogen fumarate 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 TiaGard 12.5% medicated solutions

Determine the amount of TiaGard 12.5% 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			
Net tiamulin hydrogen fumarate content: Diseases to be treated: Daily tiamulin hydrogen fumarate required per pound body weight:		Swine	One Liter 125,000 mg	Swine
		Dysenter	у	Pneumonia 10.5 mg
		3.5 mg		
Required treatment duration:		5 days		5 days
Pig Wt, Ib	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	1 bottle (1 Liter)	550 gal		183 gal
final dilution	3 bottles (3 Liters)	1650 gal		550 gal
of:	1/2 bottle (0.5 Liters)	275 gal		92 gal
Tiamulin hydrogen fumarate concentration		227 mg		681 gal
per gallon at suggested final dilution*		(60 ppm)		(180 ppm)

Number of pigs this bottle will treat for ONE day based on water consumption per pig

Net tiamulin hydrogen fumarate content: Diseases to be treated:			Five Liters
		Swine Dysentery	625,000 mg Swine y Pneumoni
•	hydrogen fumarate bound body weight:	3.5 mg	10.5 mg
Required trea	tment 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	1 bottle (5 Liters)	2750 gal	917 gal
final dilution	3 bottles (15 Liters)	8250 gal	2750 gal
of:	1/2 bottle (2.5 Liters)	1375 gal	458 gal
Tiamulin hydrogen fumarate concentration per gallon at suggested final dilution*		227 mg	681 gal
		(60 ppm)	(180 ppm)

- 1. Prepare fresh medicated drinking water every day for the 5 day treatment period.
- 2. Water medicated with TiaGard 12.5% 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.





VETERINARY STRENGTH, WHOLE-HERD TREATMENT OF SWINE DYSENTERY AND SWINE PNEUMONIA





AURORA PHARMACEUTICAL'S TIAGARD® 12.5% LIQUID CONCENTRATE is specifically

designed by veterinarians to effectively and quickly stop swine dysentery and pneumonia. TiaGard 12.5% Liquid Concentrate contains 12.5% tiamulin hydrogen fumarate and is a proven, cost-effective treatment for swine dysentery associated with Brachyspira hyodysenteriae and swine pneumonia due to Actinobacillus pleuropneumoniae.

www.aurorapharmaceutical.com

TiaGard 12.5%

EASY TO DOSE AND ADMINISTER VIA THE DRINKING WATER

Five-day dosing in drinking water with no age restrictions enables quick, effective, whole-herd treatment against both dysentery and swine pneumonia.



Administer **TiaGard® Liquid Concentrate** in the drinking water for 5 consecutive days for the treatment of swine dysentery at a dosage rate of 3.5 mg per pound of body weight. TiaGard® Liquid Concentrate is labeled for the treatment of swine pneumonia due to Actinobacillus pleuropneumoniae when given at 10.5 mg per pound of body weight.

TiaGard is a Registered Trademark of Aurora Pharmaceutical, Inc









TIAGARD® 12.5% LIQUID **CONCENTRATE PRODUCT BENEFITS**

- Equivalent active ingredient to pioneer Denagard® (tiamulin) hydrogen fumarate) at a fraction of the cost per head
- Active against Brachyspira (formerly Serpulina or Treponema) hyodysenteriae and Actinobacillus pleuropneumoniae
- Approved for use in medicated proportioners . . . no needles required, meets PQA standards
- High potency, low resistance tiamulin hydrogen fumarate is widely considered to be the most effective antimicrobial against swine dysentery caused by Brachyspira hyodysenteriae^{1,2}
- Economic impact varies based on the severity and prevalence of the disease within an operation. The combination of treatment costs and death loss can cost producers thousands of dollars a year. A significant portion of that loss also comes from low average daily gain. It is estimated a producer loses between \$11 and \$17 for every infected animal³
- One liter (1,000 mL) of TiaGard 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 (For 5L dosing, please see back label)

www.aurorapharmaceutical.com

- Five-day dosing in drinking water with no age restrictions enables quick, effective, whole-herd treatment against both dysentery and swine pneumonia
- Readily absorbed from the gut and can be found in the blood within 30 minutes after dosing
- Short withdrawal time after use (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)
- Manufactured and packaged in the USA ... no product shortages or added costs due to international production, shipping, inspection and repackaging



1L Bottle - Reorder No: 22001 5L Bottle - Reorder No: 22002

PURCHASING TIAGARD®

Contact your local Aurora Pharmaceutical, Inc. sales representative or call customer service at 1-888-215-1256 for information on TiaGard® or to answer questions about its use.

PIG WEIGHT	WATER INTAKE	SWINE DYSENTERY	SWINE PNEUMONIA	
		# OF PIGS	#OF PIGS	
20 LBS.	0.3-0.5 GAL.	1,786	595	
45 LBS.	0.4-1.1 GAL.	794	265	
75 LBS.	0.7-1.5 GAL.	476	159	
125 LBS.	1.0-2.0 GAL.	286	95	
180 LBS.	1.2-3.0 GAL.	198	66	
SUGGESTED FINAL DILUTION		SWINE DYSENTERY	SWINE PNEUMONIA	
1/2 BOTTLE (0.5L)		275 GAL.	92 GAL.	
1 BOTTLE (1L)		550 GAL.	183 GAL.	
3 BOTTLES (3L)		1,650 GAL.	550 GAL.	

For 5L dosing, please see back label.

Caution: Do not use undiluted. Do not use in animals other than swine. The effects of tiamulin on swine reproductive performance, pregnancy and lactation have not been determined.

Contraindications: Swine being treated with TiaGard® 12.5% (tiamulin) should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, salinomycin and semduramycin) as adverse reactions may occur.

The label contains complete use information including cautions, warnings and withdrawal times. Always read and follow the label and use directions.

TiaGard is a Registered Trademark of Aurora Pharmaceutical. Inc. Denagard is a Registered Trademark of Elanco Animal Health

1. Wilberts BL, Arruda PH, Warneke HL, Erlandson KR, Hammer JM, Burrough ER. Cessation of clinical disease and spirochete shedding after tiamulin treatment in pigs experimentally infected with "Brachyspira hampsonii". Res Vet Sci. 2014;97(2):342-348. 2. Krasucka D. Mitura A. Cybulski W. et al. Tiamulin hydrogen fumarate—veterinary uses and HPLC method of determination in premixes and medicated feeding stuffs. Acta Pol Pharm. 2010;67(6):682-685.

3. Almond, G., Eads, K. and Keffaber, K. 2006. "Assessment of the Therapeutic Effect of Tilmicosin in Lactation Feed." Proc. 19th IPVS Congress: 523.