

TIAGARD 12.5%- tiamulin fumarate concentrate
Aurora Pharmaceutical, Inc.

TiaGard® 12.5%
(tiamulin hydrogen fumarate)

Liquid Concentrate

12.5% Tiamulin hydrogen fumarate

Approved by FDA under ANADA # 200-717

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) mercaptoacetoxy] mutilin hydrogen fumarate, a semi-synthetic diterpene antibiotic. TiaGard 12.5% 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:

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., 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 - 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 determined.

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 been done.

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	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 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.

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. 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. 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. 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. In barrels or tanks: 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 at 381 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. 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 bottles (169 fl oz; 5000 mL)	12.5% (125.0 g) Tiamulin hydrogen fumarate

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

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>.

Restricted Drug (California): Use only as directed.



Principal Display Panel - TiaGard 12.5% 1000 mL Bottle Label

NDC 51072-092-02

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)

REORDER NO: 22001

MANUFACTURED BY:

Aurora Pharmaceutical, Inc. NORTHFIELD, MINNESOTA 55057

1-888-215-1256

www.aurorapharmaceutical.com

IN 50-1727 07/2022



NDC 51072-092-02

TiaGard[®] 12.5%

(tiamulin hydrogen fumarate)
Liquid Concentrate

12.5% Tiamulin hydrogen fumarate

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

Approved by FDA under ANADA # 200-717

REORDER NO: 22001

Manufactured by: Aurora Pharmaceutical, Inc.

Northfield, Minnesota 55057

Manufactured in the USA

IN 50-1727 07/2022



5017270722

TAKE TIME  OBSERVE LABEL
DIRECTIONS



Principal Display Panel - TiaGard 12.5% 5000 mL Bottle Label

NDC 51072-092-01

TiaGard[®] 12.5%

(tiamulin hydrogen fumarate)

Liquid Concentrate

12.5% Tiamulin hydrogen fumarate

Approved by FDA under ANADA # 200-717

One Liter (5.285 Quarts)

(169 fl oz; 5000 mL)

REORDER NO: 22002

MANUFACTURED BY:

Aurora Pharmaceutical, Inc. NORTHFIELD, MINNESOTA 55057

1-888-215-1256

www.aurorapharmaceutical.com

IN 50-1503 07/2022



NDC 51072-092-01

TiaGard[®] 12.5%

(tiamulin hydrogen fumarate)

12.5% Tiamulin hydrogen fumarate
Approved by FDA under ANADA # 200-717
Five Liter (5.285 Quarts)
(169 fl. oz; 5000 mL)

5L Liquid Concentrate

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 treatment at 3.5 mg per pound body weight and 7 days before slaughter after treatment at 10.5 mg per pound body weight. ◀

Active Ingredient: This bottle contains 21.65 oz (625.0 g) tiamulin hydrogen fumarate in solution.

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 determined.

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

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.

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 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 galvanized metal containers.

Restricted Drug (California): Use only as directed.

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) mercaptoacetoxy] mutilin hydrogen fumarate, a semi-synthetic diterpene antibiotic. TiaGard 12.5% 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.

REORDER NO: 22002
Manufactured by: Aurora Pharmaceutical, Inc.
Northfield, Minnesota 55057
Manufactured in the USA
IN 50-1503 07/2022



5015030722



TAKE TIME  OBSERVE LABEL DIRECTIONS

TIAGARD 12.5%

tiamulin fumarate concentrate

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:51072-092
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:51072-092-00	1000 mL in 1 BOTTLE		
2	NDC:51072-092-01	5000 mL in 1 BOTTLE		
3	NDC:51072-092-02	1000 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200717	03/08/2022	

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment

Name	Address	ID/FEI	Business Operations
Aurora Pharmaceutical, Inc.		832848639	manufacture

Revised: 11/2023

Aurora Pharmaceutical, Inc.