

TRIAMULOX- tiamulin hydrogen fumarate liquid
Zoetis Inc.

TriamuloxLiquid Concentrate

Active ingredient(s)

Active Ingredient

12.3% (116.4g)

Tiamulin hydrogen fumarate

Description

Triamulox (tiamulin hydrogen fumarate) 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. Triamulox 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

Triamulox, when administered in the drinking water for ve 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 Triamulox should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) 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.

Residue Warning: 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 Triamulox 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.

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		

Note:

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

Directions for preparing Triamulox Liquid Concentrate medicated solutions: Determine the amount of Triamulox 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.

Table 2 Triamulox 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:	1 bottle	512 gal	–
	3 bottles	–	512 gal
	½ pint (8 oz)	128 gal	43 gal
	1 ½ pints (24 oz)	–	128 gal
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 Triamulox Liquid Concentrate in medicated proportioners: One quart of Triamulox 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 of tiamulin hydrogen fumarate per gallon to 512 gallons of drinking water for treatment of swine dysentery. Three quarts of Triamulox 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 Triamulox 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 Triamulox 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 Triamulox diluted with water to make one gallon of stock solution and this stock 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 Triamulox 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 Triamulox 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 Triamulox 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

How Supplied

Container Size

Quart Bottles

(32 fl oz.; 946 ml)

Active Ingredient

12.3% (116.4g)

Tiamulin hydrogen fumarate

Storage

Protect from direct sunlight. Store between 20°-25°C (68°-77°F) with excursions permitted between 15°-40°C (59°-104°F)

other information

Observe expiration date.

Restricted Drug (California): Use only as directed

Approved by FDA under ANADA # 200-512

Manufactured and Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

Product of China

Revised: August 2020

40031120

Principal Display Panel

Triamulox


(tiamulin hydrogen fumarate)

Liquid Concentrate

12.3% Tiamulin hydrogen fumarate

Approved by FDA under ANADA # 200-512

One Quart (32 oz; 946 mL)

<p>Warning: Keep out of reach of children. Avoid direct contact with the skin. Direct contact with skin or mucous membranes may cause irritation.</p> <p>Residue Warning: 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.</p> <p>Active Ingredient: This bottle contains 4.10 oz (116.4 g) tiamulin hydrogen fumarate in solution.</p> <p>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.</p> <p>Contraindication: Swine being treated with Triamulox (tiamulin hydrogen fumarate) Liquid Concentrate should not have access to feeds containing polyether ionophores (e.g., monensin, lasalocid, narasin, salinomycin and semduramicin) as adverse reactions may occur.</p> <p>Indications: Treatment of swine dysentery associated with <i>Brachyspira</i> (formerly <i>Serpulina</i> or <i>Treponema</i>) <i>hyodysenteriae</i> and swine pneumonia due to <i>Actinobacillus pleuropneumoniae</i>, susceptible to tiamulin.</p>	<p>Triamulox™ (tiamulin hydrogen fumarate)</p> <p>Liquid Concentrate</p> <p>12.3% Tiamulin hydrogen fumarate</p> <p>ANADA 200-512, Approved by FDA</p> <p>One Quart (32 fl oz; 946 mL)</p> <p>zoetis</p>	<p>Use Directions: 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.</p> <p>Protect from direct sunlight. Store between 20°-25°C (68°-77°F) with excursions permitted between 15°-40°C (59°-104°F).</p> <p>Restricted Drug (California): Use only as directed</p> <p>zoetis Distributed by: Zoetis Inc. Kalamazoo, MI 49007 Product of China</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>0 87219 11071 3</p>
		<p>50220600</p> <p>Lot Exp.</p> <p>LABEL LOT ID MM/YYYY</p>

TRIAMULOX

tiamulin hydrogen fumarate liquid

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:54771-8729
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TIAMULIN FUMARATE (UNII: ION1Q02ZCX) (TIAMULIN - UNII:E38WZ4U54R)	TIAMULIN FUMARATE	116.4 g in 946 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8729-0	946 mL in 1 BOTTLE		
2	NDC:54771-8729-1	4730 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200512	10/10/2016	

Labeler - Zoetis Inc. (828851555)

Revised: 10/2020

Zoetis Inc.