ARTWORK/PACKAGING/PRODUCTION			
File Name:	8BIM060_Bimagard_1L_Out.ai		
Artwork Date:	November 6, 2019	Version v.21	REV 11/19
Item Size:	4.5" (H) x 4.0" (W)		
Dieline:	Lofton - 4.5x4 4 panel vfo		

CMYK	Scale:	100%	
CMYK + SPOT	Label ✓	Carton	Insert
✓ SPOT COLORS (Pantone)	Content Smallest Font:	6 pt	
PMS Black 100%	Registration Smallest Font:	6 pt	
PMS 143	Verified Dieline	Y	N
PMS PMS	Verified Batch Area	Y	N
PMS PMS	Mock-Up Approved	Y	N
ONSERT / COPY LIMIT / DIELINE	Unwind #	1 2 3 4	
BLEED LIMIT / ONSERT PLACEMENT TOLERANCE / NO VARNISH			

4.0″

4.5″

Web Direction
Unwind

Front Panel of Onsert

Base Print without Onsert

4.0″

4.5″

Bimeda®

PULL

BimaGard™ 12.5%

(tiamulin hydrogen fumarate)

Liquid Concentrate *12.5% Tiamulin hydrogen fumarate*

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 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 **4.33 oz (125.0 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 BimaGard™ 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: 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 onsert for complete directions; read completely.

Protect from direct sunlight. Store container in an upright position. Store at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C - 30°C (59°F - 86°F).

Restricted Drug (California): Use only as directed

Approved by FDA under ANADA # 200-546

Net Contents:
1 Liter (1.057 Quarts)
(33.8 fl oz; 1000 mL)

BimaGard™ is a Trademark of Bimeda, Inc.
Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058, USA
www.bimeda.com

1BIM060 8BIM060 Rev. 11/19

LOT
EXP

TAKE TIME
OBSERVE LABEL DIRECTIONS

4.5″

Directions for using BimaGard™ 12.5%

In medicated proportioners: One liter of BimaGard™ 12.5% (tiamulin hydrogen fumarate) 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 BimaGard™ 12.5% 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 BimaGard™ 12.5% 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 BimaGard™ 12.5% 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 Ingredient
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 container in an upright position. Store at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C - 30°C (59°F - 86°F).

Approved by FDA under ANADA # 200-546

Observe expiration date.

TAKE TIME
OBSERVE LABEL DIRECTIONS

Manufactured By:
Bimeda, Inc.
Le Sueur, MN 56058, USA
www.bimeda.com

N.A. Corp. Address:
Bimeda, Inc.
One Tower Lane,
Oakbrook Terrace, IL 60181

Bimeda®

Bimeda®

BimaGard™ 12.5%
(tiamulin hydrogen fumarate)
Liquid Concentrate *12.5% Tiamulin hydrogen fumarate*

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 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 **4.33 oz (125.0 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 BimaGard™ 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: 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 onsert for complete directions; read completely.

Protect from direct sunlight. Store container in an upright position. Store at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C - 30°C (59°F - 86°F).

Restricted Drug (California): Use only as directed

Approved by FDA under ANADA # 200-546

Net Contents:
1 Liter (1.057 Quarts)
(33.8 fl oz; 1000 mL)

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1BIM060 8BIM060 Rev. 11/19

LOT
EXP

3.375″ 3.4375″ 3.4375″ 3.5″

Front Panel of Onsert

Description:
BimaGard™ 12.5% (tiamulin hydrogen fumarate) 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. BimaGard™ 12.5% 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:
BimaGard™ 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 BimaGard™ 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 body weight and 7 days before slaughter after 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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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 BimaGard™ 12.5% medicated solutions
Determine the amount of BimaGard™ 12.5% (tiamulin hydrogen fumarate) 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 Bimagard 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.

4.5″

Inside Front Panel of Onsert 3.5″ 3.4375″ 3.4375″ 3.375″