AMPROMED FOR CALVES- amprolium solution Bimeda Inc., Division of Cross Vetpharm Group

AmproMed™ FOR CALVES

(amprolium)

9.6% Oral Solution

Coccidiostat

FOR ORAL USE IN ANIMAL ONLY

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Restricted Drug (California) - Use Only as Directed

ANADA 200-482, Approved by FDA

Net Contents:

1Gallon (128 fl oz) (3.785 L)

ACTIVE INGREDIENT: amprolium.....9.6%

INDICATIONS: An aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in calves. For a satisfactory diagnosis a microscopic examination of the feces should be done before treatment. When treating outbreaks, drug should be administered promptly after diagnosis is determined.

DOSAGE AND ADMINISTRATION:

USE DIRECTIONS: There are 96 mg of Amprolium in every 1 ml of AmproMed™ FOR CALVES

5 Day Treatment Protocol	21 Day Prevention Protocol
Daily Dosage: 10 mg Amprolium/kg	Daily Dosage: 5 mg Amprolium/kg
(10 mg per 2.2 lb body weight)	(5 mg per 2.2 lb body weight)
1 fl oz = 29.57 mL	8 fl oz = $\frac{1}{2}$ pint (236.56 mL)
1 fl oz = 2 measuring tablespoonfuls	16 fl oz = 1 pint (473.12 mL)

IN DRINKING WATER

Mix AmproMed™ FOR CALVES daily with fresh drinking water.

5-DAY TREATMENT: Add AMPROMED™ FOR CALVES to drinking water at the rate of 16 fl oz/100 gallon. At the usual rate of water consumption this will provide an intake of approximately 10 mg Amprolium/kg (2.2 lb) body weight. Offer this solution as the only source of water for 5 days. Use on a herd basis only; when one or more calves show signs of coccidiosis, it is likely that the rest of the group has been exposed, and all calves in the group should be treated.

21-DAY PREVENTION: During periods of exposure or when experience indicates that coccidiosis is likely to be a hazard, add AMPROMEDTM FOR CALVES to drinking water at the rate of 8 fl oz/100 gallon. At usual rates of water consumption, this will provide an intake of approximately 5 mg amprolium/kg (2.2 lb) body weight. Offer this solution as the only source of water for 21 days.

AS A DRENCH: AMPROMED™ FOR CALVES drench solutions may be stored in a clean, labeled

container for up to 3 days.

5-DAY TREATMENT: Add 3 fl oz AMPROMED™ FOR CALVES to 1 pt (16 oz) of water and, with a dosage syringe, give 1 fl oz of this drench solution for each 100 lb (45 kg) body weight. This will provide a dose of approximately 10 mg amprolium/kg (2.2) body weight. Give daily for 5 days. Use on a herd basis only: when one or more calves show signs of coccidiosis, it is likely that the rest of the group has been exposed, and all calves should be Treated.

21-DAY PREVENTION: During periods of exposure or when experience indicates that coccidiosis is likely to be a hazard, add 1 1/2 fl oz of AMPROMEDTM FOR CALVES to 1 pt (16 fl oz) of water and, with a dose syringe, give 1 fl oz of this solution for each 100 lb (45 kg) body weight. This will provide a dose of approximately 5 mg amprolium/kg (2.2 lb) body weight. Give daily for 21 days.

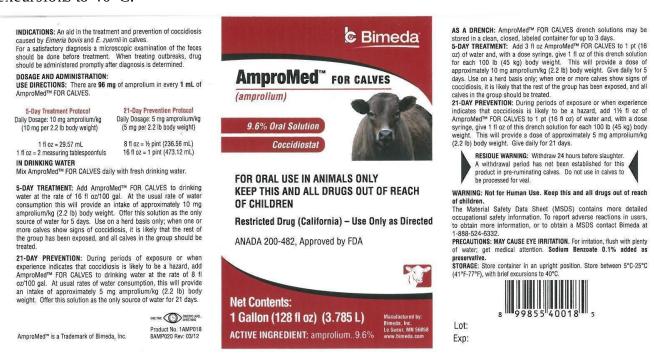
RESIDUE WARNING: Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

WARNING: Not for Human Use. Keep this and all drugs out of reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reaction in users, to obtain more information, or to obtain a MSDS contact Bimeda at 1-888-524-6332.

PRECAUTIONS:MAY CAUSE EYE IRRITATION. For irritation, flush with plenty of water; get medical attention. **Sodium Benzoate 0.1% add as preserve.**

STORAGE: Store container in an upright position. Store between 5°C - 25°C (41°F - 77°F), with brief excursions to 40°C.



AMPROMED FOR CALVES amprolium solution Product Information Product Type OTC ANIMAL DRUG LABEL Item Code (Source) NDC:61133-8251 Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMPROLIUM (AMPROLIUM ION)	AMPROLIUM ION	96 mg in 1 mL
		8

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61133-8251-3	3785 mL in 1 JUG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200482	07/30/2012	

Labeler - Bimeda Inc., Division of Cross Vetpharm Group (060492923)

Registrant - Bimeda, Inc., Division of Cross Vetpharm Group (060492923)

Establishment			
Name	Address	ID/FEI	Business Operations
Bimeda, Inc., Division of Cross Vetpharm Group		060492923	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Jiuzhou		654682061	api manufacture

Revised: 7/2013 Bimeda Inc., Division of Cross Vetpharm Group