

AMPROMED FOR CALVES- amprolium solution
Bimeda Inc.

AmproMed™ FOR CALVES
(amprolium)

9.6% Oral Solution Coccidiostat

Restricted Drug (California) - Use Only as Directed

Approved by FDA under ANADA # 200-482

Net Contents:

1 Gallon (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:

5-Day Treatment Protocol	21-Day Prevention Protocol
Daily Dosage: 10 mg amprolium/kg (10 mg per 2.2 lb body weight)	Daily Dosage: 5 mg amprolium/kg (5 mg per 2.2 lb body weight)

USE DIRECTIONS: There are **96 mg** of Amprolium in every **1 mL** of AmproMed FOR CALVES

1 fl oz = 29.57 mL	8 fl oz = ½ pint (236.56 mL)
1 fl oz = 2 measuring tablespoons	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 9.6% Oral Solution 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 AMPROMED FOR CALVES 9.6% Oral Solution to drinking water at the rate of 8 fl oz/100 gal. 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, closed labeled container for up to 3 days.

5-DAY TREATMENT: Add 3 fl oz AMPROMED FOR CALVES 9.6% Oral Solution to 1 pt of water and, with a dose 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 lb) 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 AMPROMED FOR CALVES 9.6% Oral Solution to 1 pt 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 WARNINGS: 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.

PRECAUTIONS: FOR ORAL USE IN ANIMALS ONLY. MAY CAUSE EYE IRRITATION. For irritation, flush with plenty of water; get medical attention.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse drug events, for technical assistance or to obtain a copy of the 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.

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

Sodium Benzoate 0.1% add as preservative.

Manufactured by:

Bimeda, Inc.

Le Sueur, MN 56058

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DOSE AND ADMINISTRATION:

5-Day Treatment Protocol
Daily Dosage: 10 mg amprolium/kg
(10 mg per 2.2 lb body weight)

21-Day Prevention Protocol
Daily Dosage: 5 mg amprolium/kg
(5 mg per 2.2 lb body weight)

USE DIRECTIONS: There are 96 mg of amprolium in every 1 mL of AmproMed FOR CALVES.

1 fl oz = 29.57 mL
1 fl oz = 2 measuring tablespoons

8 fl oz = ½ pint (236.56 mL)
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 9.6% Oral Solution to drinking water at the rate of 16 fl oz/100 gal. 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.

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AmproMed® is a Trademark of Bimeda, Inc.

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



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21-DAY PREVENTION: During periods of exposure or when experience indicates that coccidiosis is likely to be a hazard, add 1½ fl oz of AmproMed FOR CALVES 9.6% Oral Solution to 1 pt of water and, with a dose syringe, give 1 fl oz of this drench 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.

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Sodium Benzoate 0.1% added as preservative.

Lot: Exp:

AMPROMED FOR CALVES

amprolium solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:61133-8251
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPROLIUM (UNII: 95CO6N199Q) (AMPROLIUM ION - UNII:H2T307KMZR)	AMPROLIUM ION	96 mg in 1 mL

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		
2	NDC:61133-8251-4	473 mL in 1 BOTTLE		

Marketing Information

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

Labeler - Bimeda Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda, Inc.		060492923	manufacture

Revised: 7/2022

Bimeda Inc.