COCCIAID FOR CALVES- amprolium solution Aurora Pharmaceutical, Inc

CocciAid® for Calves

(amprolium)

9.6% Oral Solution Coccidiostat

INDICATIONS FOR USE: An aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii* 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 CocciAid for Calves 9.6% Solution.

1 fl oz = 29.57 mL 8 fl oz = 1/2 pint (236.56 mL)

1 fl oz = 2 measuring tablespoons 16 fl oz = 1 pint (473.12 mL)

IN DRINKING WATER

Mix CocciAid for Calves daily with fresh drinking water.

5-DAY TREATMENT: Add CocciAid 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.

21-DAY PREVENTION: During periods of exposure or when experience indicates that coccidiosis is likely to be a hazard, add CocciAid 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.

CocciAid® for Calves is a registered trademark of Aurora Pharmaceutical, Inc.

AS A DRENCH

CocciAid 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 CocciAid 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 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 1 1/2 fl oz of CocciAid 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.

Use as the sole source of amprolium.

WITHDRAWAL PERIODS AND RESIDUE WARNINGS: Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

USER SAFETY WARNINGS: NOT FOR HUMAN USE. Keep this and all drugs out of the reach of children.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Aurora Pharmaceutical at 1-888-215-1256 or www.aurorapharmaceutical.com. 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.

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

STORAGE: Store between 5°-25°C (41°-7°F) with brief excursions to 40°C.

Benzoic acid 0.1% added as preservative.

Restricted Drug (California) - Use Only as Directed

CocciAid® for Calves

(amprolium)

9.6% Oral Solution Coccidiostat

Net Contents: 1 gal. (128 fl. oz) (3,785 ml) **Active Ingredient:** amprolium......9.6% Approved by FDA under ANADA # 200-780

Distributed by: Aurora Pharmaceutical, Inc. Northfield, MN 55057

IN 50-1644 rev 03/2024



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DOSAGE 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)

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IN DRINKING WATER
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USER SAFET WARMINGS NOT FOR HUMAN U.S. Keep this and all drugs out of the reach of children. To report suspected adverse drug event, for technical assistance or to obtain a copy of the scale plus tables (105), contact Aurear Pharmaceutical at 1-3882-51-2560 or wavacorapharmaceutical contact and the scale plus tables (105), contact Aurear Pharmaceutical at 1-388-251-2560 or wavacorapharmaceutical contact and the scale plus tables (105) and tables (105) FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

PRECAUTIONS: FOR ORAL USE IM ANIMALS ONLY. MAY CAUSE EYE IRRITIATION. For irritations, flush with plenty of views pet medical astronomy.

STORAGE: Store between 5°-25°C (41°-77°F) with brief excursions to 40°C.

Benzoic acid 0.1% added as preservative. Restricted Drug (California) - Use Only as Directed

COCCIAID FOR CALVES

amprolium solution

Product Information

Product Type OTC ANIMAL DRUG **Item Code (Source)** NDC:51072-110

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

AMPROLIUM (UNII: 95CO6N199Q) (AMPROLIUM ION - UNII:H2T307KMZR) AMPROLIUM 96 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51072-110-00		3785 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANADA	ANADA200780	05/08/2024	

Labeler - Aurora Pharmaceutical, Inc (832848639)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dayang Biotech Group Co., Ltd.		420600785	api manufacture

Revised: 5/2024 Aurora Pharmaceutical, Inc