

DATE OF APPROVAL LETTER: JUL 7 2000

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 95-735

Free Choice Monensin Mineral Granules
Type C Medicated Feed

“For the prevention and control of coccidiosis caused by *Eimeria bovis* and
E. zuernii.”

Sponsored by:
ELANCO ANIMAL HEALTH

FOIS 1

I. GENERAL INFORMATION

NADA Number: 095-735

Sponsor: Elanco Animal Health
A Division of Eli Lilly and Co.
Lilly Corporate Center
Indianapolis, Indiana, 46285

Established Name: monensin sodium

Trade Name: RUMENSIN® 80 Type A Medicated Article
(Free Choice Monensin Mineral Granules Type C
Medicated Feed)

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: This supplement provides for the addition of the claim "for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*" to the Free Choice Monensin Mineral Granules Type C Medicated Feed label.

II. INDICATIONS FOR USE

For increased rate of weight gain and the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

- A. *Dosage Form*: RUMENSIN® 80 is a Type A Medicated Article available in 50-lb bags containing 80 g monensin sodium/lb. The Monensin Mineral Granule is a Type C Free Choice feed containing 1620 g monensin sodium/ton.
- B. *Route of Administration*: Orally, as a mineral supplement
- C. *Recommended Dosage*: Feed continuously on a free choice basis at the rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 mg/hd/day.

IV. EFFECTIVENESS

Data supporting the effectiveness of previously approved indications are discussed in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 22, 1990, and December 16, 1998). No new data were required for the approval of this supplement.

V. TARGET ANIMAL SAFETY

Data supporting the target animal safety of RUMENSIN® Type A Medicated Article are summarized in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 23, 1995, and July 15, 1996). No additional data were required for approval of this supplement.

VI. HUMAN FOOD SAFETY

Data supporting the human food safety of RUMENSIN® 80 Type A Medicated Article are summarized in the original FOI Summary for NADA 095-735.

VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental application satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations to enable FDA to revise 21 CFR 558.355(f)(3)(x) to provide for the safe and effective use of Monensin Type A medicated article to make free choice mineral granules Type C medicated feeds for the prevention and control of coccidiosis and increased rate of weight gain in pasture cattle.

A tolerance of 0.05 ppm for negligible residues of monensin in the edible tissues of cattle and the ADI of 12.5 mcg/kg bw/day are codified at 21 CFR 556.420. A withdrawal time before slaughter is not required.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a re-evaluation of the safety or effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug

involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

RUMENSIN® 80 Type A Medicated Article is under U.S. patent numbers:

Patent Number	Expiration Date
4366168	September 21, 2001
4405609	January 22, 2001
4468380	August 28, 2001
4764534	August 16, 2005

VIII. APPROVED LABELING (Attached)

1. Type C Bluebird labeling
2. Type A Medicated Article labeling

DV 5685 AMB

ELANCO
Rumensin
80
AF 0480-50B

ELANCO* AF 0480-50B

For Animal Use Only

Rumensin[®]
Monensin Premix, USP
80

Net Weight **50 lbs**
(22.68 kg)

Type A Medicated Article

Do Not Feed Undiluted

Feedlot Cattle: A. For improved feed efficiency (cattle fed in confinement for slaughter).
B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*;

Pasture Cattle (Slaughter, stocker, feeder, dairy and beef replacement heifers):
A. For increased rate of weight gain.
B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*;

Mature Reproducing Beef Cows:
A. For improved feed efficiency when receiving supplemental feed.
B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*;

Goats: A. For the prevention of coccidiosis caused by *Eimeria crandallis*, *Eimeria christenseni*, and *Eimeria ninakohlyakimovae* in goats maintained in confinement.

Calves (excluding veal calves):
A. For the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

CAUTION: Do not allow horses or other equines access to feeds containing **Rumensin**. Ingestion of **Rumensin** by horses has been fatal. **Rumensin** medicated feed is intended for use in cattle or in goats. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of **Rumensin** has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of **Rumensin** recommended in the feeding directions as reduced average daily gains may result. Do not feed to lactating dairy cows. Do not feed to lactating goats. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

WARNING: When mixing and handling **Rumensin 80**, use protective clothing, impervious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with water.

Avoid moisture and excessive heat. Not to be used after date printed at top of bag.
*Elanco®, Rumensin®, and the diagonal color bar are trademarks of Eli Lilly and Company.

Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285, USA

Questions or Comments Call 1-800-428-4441
Internet Address: <http://www.elanco.com>

AF 0480-50b

ELANCO

Rumensin[®] 80

Directions for Use Read All Directions Carefully Before Mixing and Feeding

Active Drug Ingredients: Monensin Granulated, USP, 80 g monensin activity per pound.

I. Feedlot Cattle:

- A. For improved feed efficiency.** Feeding Directions: Thoroughly mix Rumensin 80 to make one ton of complete feed that provides 5 to 30 g/ton monensin on a 90% dry matter basis (Table 1). Feed complete feed (5 to 30 g/ton) continuously to growing finishing beef cattle to provide not less than 50 nor more than 360 mg monensin activity per head per day.
- B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.** Feeding Directions: Feed continuously at the rate of 0.14 to 0.42 mg per pound body weight per day, depending upon severity of challenge, up to a maximum of 360 mg of monensin per head per day.

II. Pasture Cattle (slaughter, stocker, and feeder, dairy and beef replacement heifers):

- A. For increased rate of weight gain.** Feeding Directions: Feed at the rate of not less than 50 nor more than 200 mg per head per day in not less than one pound of Type C Medicated Feed; or after the 5th day, feed at the rate of 400 mg per head per day every other day in not less than 2 pounds of Type C Medicated Feed. The monensin activity in the pasture Type C Medicated Feed must be between 25 and 400 grams per ton. During the first 5 days, cattle should receive no more than 100 mg per day contained in not less than 1 pound of feed. Do not self feed.
- B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.** Feeding Directions: Feed at a rate to provide 0.14 to 0.42 mg per pound body weight per day depending upon severity of challenge up to a maximum of 200 mg per head per day. During the first 5 days, cattle should receive no more than 100 mg per day contained in not less than 1 pound of feed.

C. Free-Choice (Self-Fed) Supplements

Free-choice supplements must be formulated to provide not less than 50 nor more than 200 mg monensin per head per day (manufacturers of Type C free-choice feeds from this product require a Medicated Feed License Application approved by the FDA)

III. Mature Reproducing Beef Cows (on pasture or in dry lot):

- A. For improved feed efficiency when receiving supplemental feed.** Feeding Directions: Feed 50 to 200 mg per head per day. Blend into a minimum of 1 pound of Type C Medicated Feed and either hand feed or mix into the total ration. Feed (other than the Type C Medicated Feed containing Rumensin) can be restricted to 95% (of normal requirements) when 50 mg of monensin activity is fed, and to 90% at 200 mg. Cows on pasture or in dry lot must receive a minimum of 1 pound of Type C Medicated Feed per head per day. Additionally, a minimum of 16 pounds (air-dry basis) of roughage such as silage, haylage, ammoniated straw, hay or equivalent feedstuffs should be fed in order to meet NRC recommendations for mature reproducing beef cows to gain 0.25 to 0.75 pounds per head per day. Standing, dried winter range forage may not be of adequate quality to result in improved efficiency when supplemented with Rumensin. During the first 5 days, pastured cattle should receive no more than 100 mg per day contained in not less than 1 pound of feed. Do not self feed.
- B. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.** Feeding Directions: Feed at a rate to provide 0.14 to 0.42 mg per pound body weight per day depending upon severity of challenge up to a maximum of 200 mg per head per day. During the first 5 days, pastured cattle should receive no more than 100 mg per day contained in not less than 1 pound of feed.

IV. Goats

- A. For prevention of coccidiosis.** Feeding Directions: Feed complete feed (20 g/ton) continuously to goats as the sole ration. Feed only to goats maintained in confinement.

V. Calves (excluding veal calves):

- A. For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.** Feed at a rate of 0.14 to 1.00 mg per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 mg of monensin per head per day.

VI. Type B or C Medicated Feed Mixing Directions (Dry and Liquid)

A. Dry or Liquid

Thoroughly mix the following amounts of Rumensin 80 to make one ton of Type B or C Medicated Feed to provide the levels shown in Table 1. Dry Only - An intermediate blending step should be performed to insure an adequate mix.

B. Liquid Limitations

- The supplement pH must be between 4.3-7.1.
- Stored liquid Type B Medicated Feeds containing Rumensin: Recirculate or agitate liquid Type B Medicated Feeds daily even when no Type B feed is used and immediately prior to use for no less than 10 minutes moving no less than 10% of the contents from the bottom of the tank!

CAUTION: Inadequate mixing (recirculation or agitation) of Rumensin Liquid Type B or C Medicated Feeds has resulted in increased Rumensin concentration which has been fatal to cattle and could be fatal to goats.

Table 1. MIXING DIRECTIONS

Amount of Rumensin 80 per ton		Monensin Activity in Medicated Feed	
lbs	grams	grams/ton	mg/lb feed
0.06	27	5	2.5
0.25	113	20	10
0.37	168	30	15
5.0	2268	400	200
15.0	6804	1200	600



NET WEIGHT ON BAG OR BULK

**FREE CHOICE MONENSIN MINERAL GRANULES
TYPE C MEDICATED FEED**

For increased rate of weight gain and the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

Active Ingredient

Monensin (as monensin sodium).....1620 g/ton

Guaranteed Analysis

Salt, not more than.....	26.0%
Salt, not less than.....	22.0%
Calcium, not more than.....	10.5%
Calcium, not less than.....	9.0%
Phosphorus, not less than.....	6.0%
Magnesium, not less than.....	x.x%
Potassium, not less than.....	x.x%
Sodium ^a , not more than.....	x.x%
Sodium ^a , not less than.....	x.x%
Copper, not less than.....	xx ppm
Selenium, not less than.....	xx ppm
Zinc, not less than.....	xx ppm
Vitamin A, not less than.....	IU/lb

^a Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee

Ingredients

Salt, dried cane molasses, monocalcium phosphate, ground limestone or calcium carbonate, dicalcium phosphate, processed grain by-products, cane molasses, and mineral oil (include microingredients as appropriate). Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials

Feeding Directions

For free choice feeding to pastured cattle only. Feed continuously on a free-choice basis at the rate of 50 to 200 milligrams per head per day. Place in covered mineral feeders located near the animals' water supply and/or loafing area. Provide one feeder for each 20 head. Fill feeders with a quantity of Monensin Mineral Supplement that will be consumed in seven days. It is essential to offer enough feeding stations to insure that all animals have free access at all times to the Monensin Mineral Supplement. Cattle should consume 1 to 4 ounces per head daily which will provide the approved effective intake of 50 to 200 mg monensin.

NOTE: Adequate consumption is dependent on good pasture conditions.

Caution

During the first 5 days of feeding, cattle should receive no more than 100 mg/hd/day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or water deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feeds containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. The effectiveness of this product in cull cows and bulls has not been established. Consumption by unapproved species may result in toxic reactions.

Warning

Do not feed to lactating dairy cattle.

Manufactured by:
Blue Bird Feed Mills
Robin, IN 12345

Lot No. _____

01/00