HFA-305 (Docketts Management Br.)

Date of Approval: DEC 16 1998

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 095-735

RUMENSIN® 80 Type A Medicated Article
(monensin sodium)

Sponsored by

ELANCO ANIMAL HEALTH

NADA 095-735

I. GENERAL INFORMATION

NADA Number: 095-735

Sponsor: Elanco Animal Health
A Division of Eli Lilly& Company
2001 W. Main Street
Greenfield, IN 46140

Established Name: monensin sodium

Trade Name: RUMENSIN® 80 Type A medicated article

Marketing Status: over-the-counter (OTC)

Effect of Supplement: Previously approved indications are discussed in the FOI SUMMARY for NADA 095-735. Type B and Type C medicated feeds containing monensin at 10 to 30 g/ton are approved for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in confined cattle.

This supplement provides for: (A) a lower effective dose based on body weight (O. 14 to 0.42 mg/lb body weight/day) for the prevention and control of coccidiosis in feedlot cattle, pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers), and mature reproducing beef cows, and (B) the use of monensin at 10 to 200 g/ton for the prevention and control of coccidiosis in calves (except for veal calves) at a dose based on body weight (O. 14 to 1.0 mg/lb body weight/day) up to a maximum of 200 mg/hd/day.

II. INDICATIONS FOR USE

Cattle: For improved feed efficiency in cattle fed in confinement for slaughter and mature reproducing beef cattle receiving supplemental feed, for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers), and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle fed in confinement, pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers), mature reproducing beef cows (on pasture or in dry lot), and calves.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

A. Dosage Form: RUMENSIN® 80 is a Type A medicated article available in a 50-lb. bag containing 80 g monensin sodium/lb.

B. Route of Administration: Orally, in feed.

C. Recommended Dosage for the Prevention and Control of Coccidiosis:

Feedlot Cattle: Feed continuously at the rate of 0.14 to 0.42 mg/lb body weight (bw)/day, depending on severity of challenge, up to a maximum of 360 mg/hd/day.

Pasture Cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): Feed at a rate to provide 0.14 to 0.42 mg/lb bw/day depending upon severity of challenge up to a maximum of 200 mg/hd/day. During the first 5 days, cattle should receive no more than 100 mg/day contained in not less than 1 lb feed.

Mature Reproducing Beef Cows: Feed at a rate to provide 0.14 to 0.42 mg/lb bw/day depending upon severity of challenge up to a maximum of 200 mg/hd/day. During the first 5 days, pastured cattle should receive no more than 100 mg/day contained in not less than 1 lb feed.

Calves (except for veal calves): Feed at a rate of 0.14 to 1.0 mg/lb bw/day, depending upon severity of challenge, up to a maximum of 200 mg/hd/day.

IV. EFFECTIVENESS

Effectiveness data collected in feedlot cattle for the approved indication for prevention and control of coccidiosis was determined to provide adequate evidence of the effectiveness of monensin for this same indication in mature reproducing beef cows and pasture cattle. Data supporting the effectiveness of previously approved indications are summarized in the FOI SUMMARY for NADA 095-735. Additional data was provided to satisfy concerns for an effective dose range in young animals.

A. Type of Study: an effective dose range confirmation study was conducted for the prevention and control of coccidiosis in calves by the following individual:

Kelly F. Lechtenberg, D.V.M, Ph.D.
Midwest Veterinary Services, Inc.
Oakland, NE 68045

B. General Design

1. Purpose: To determine the effective dose range of monensin for the prevention and control of coccidiosis in calves.

2. Animals and Housing: Ninety-six male Holstein calves **(24/treatment group)** were randomly assigned to building, location (blocks) within building, and treatment group; five died prior to treatment initiation. The 91 calves remaining were started on treatment at approximately 9.5 weeks of age.

3. Infections: One week following initiation of monensin feeding, calves were orally challenged with a total of approximately 300,000 oocysts/calf (approximately 231,000 *E. bovis* oocysts, *54,000 E. zuernii* oocysts, and 15,000 miscellaneous *Eimeria* species). Infection was confirmed by fecal oocyst counts, fecal scores, and daily observations.

4. Dosage Form, Dose, and Route of Administration: Commercially available RUMENSIN® 80 Type A medicated article was incorporated into complete feeds at levels of O, 10, 20, and 30 g/ton (90°/0 dry matter basis) for oral administration. Feed was offered at levels corresponding to 0,0.14,0.28, and 0.42 mg/lb bw/day or O, 25.1, 49.5, and 74.6 mg/hd/day. The duration of the trial was 35 days (7 days pre-challenge and 28 days post-challenge).

5. Parameters Measured: Primary efficacy variables were average daily body weight gain, fecal oocyst counts, and fecal scores. Secondary efficacy variables were gain efficiency and daily dry matter feed intake.

C. Results: Least squares means are summarized below in Table 4.1.

Table 4.1. Results expressed as least squares means.

Variable	Monensin Level (mg/lb bw/day)[a]			
	o	0.14	0.28	0.42
Average daily weight gain (lbs/day)	1.36	1.86	1.65	1.59
Total oocysts, $\log_{10}$ (oocyst/g feces/day)	1.47	0.42	0.31	0.22
E. bovis oocysts, $\log_{10}$ (oocyst/g feces/day)	1.40	0.39	0.29	0.19
E. zuernii oocysts, $\log_{10}$ (oocyst/g feces/day)	0.89	0.14	0.09	0.09
Fecal scores, square root (scale O to 4) [b]	0.22	0.13	0.16	0.12
Average daily intake (lbs dry matter/day)	4.45	4.63	4.56	4.63
Gain efficiency (lb gain/lb dry matter)	0.25	0.39	0.38	0.35
Mortality (number died/initial number)[c]	1/24	1/23	0/21	1/23

'**Values** for average daily gain, fecal scores, intake, and gain efficiency are treatment group least squares means averaging over weeks 1 through 4 post-challenge.

^{b}0 = normal, 1 = slight diarrhea, 2 = diarrhea, 3 = diarrhea **with** blood, 4 = diarrhea with mucus and/or tissue

'Mortality data were not analyzed statistically.

Monensin prevented significant reduction in average daily gain at 0.14 mg/lb bw/day ($P = 0.004$). Oocyst counts in all treated groups were significantly reduced relative to controls ($P < 0.001$) with additional reduction in total oocyst counts and *E. bovis* counts at higher monensin doses. Although not statistically significant ($P > 0.05$), a numeric decrease in fecal scores occurred in all monensin treated groups relative to controls.

Among secondary efficacy variables, gain efficiency was significantly greater than controls at the 0.14 mg/lb bw/day dose level ($P = 0.009$) and was relatively constant at higher monensin levels. The efficacy demonstrated in both the primary and secondary variables occurred primarily during the third and fourth weeks post challenge, which coincided with clinical signs of coccidiosis.

D. Adverse Reactions: There were no adverse reactions to treatment.

E. Conclusions: The data support an effective dose range of 0.14 to 0.42 mg/lb bw/day of RUMENSIN® 80 for the prevention and control of infections of *Eimeria bovis* and *E. zuernii*.

V. ANIMAL SAFETY

Data supporting the target animal safety of previously approved indications for RUMENSIN® 80 Type A medicated article and this supplement are summarized in the FOI SUMMARY for NADA 095-735.

VI. HUMAN SAFETY

Data supporting the human food safety of RUMENSIN® 80 Type A medicated article are summarized in the FOI SUMMARY for NADA 095-735.

As part of the approval of this supplement, the Agency has taken the opportunity to update the human food safety information on this product and to codify an Acceptable Daily Intake (ADI) of 12.5 ug/kg bw/day.

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that RUMENSIN® 80 Type A medicated article is safe and effective for the indications stated on the product labeling.

An accurate diagnosis can be made with a reasonable degree of certainty by the layman and the directions and conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall retain over-the-counter marketing status.

In accordance with21 CFR 514. 106(b)(2)(iii), this is a Category II change that did not require a reevaluation of the safety or effectiveness data in the parent application. A tolerance of 0.05 ppm for negligible residues of monensin in the edible tissues of cattle and goats is codifiedat21 CFR 556.420. The previously established ADI of 12.5 ug/kg bw/day is now codified. A withdrawal time before slaughter is not required.

In accordance with21 CFR 25.33(a)(1) & (7), this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental approval for food-producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains 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 THREE years of marketing exclusivity applies only to the new indication for a weight-based dose range for which the supplemental application was approved in calves.

RUMENSIN® 80 Type A medicated article is held by Elanco Animal Health under the following U.S. patent numbers:

Number	Expiration Date	Number	Expiration Date
4218438	**02/14/99**	**4405609**	0 1/22/01
4333919	09/12/99	4468380	08/28/01
4366168	09/21/0 1	4764534	08/16/05

VIII. APPROVED LABELING (attached)

Draft labeling is attached to this document.

A. Facsimile labeling for Type A medicated article:

. RUMENSIN® 80 Type A Medicated Article (monensin premix, USP)

B. Specimen labeling (Blue Bird label) for Type B medicated feeds:

- BLUEBIRD COCCI PELLET Type B Medicated Feed (300 to 2000 g/ton)
- BLUEBIRD MEDICATED CATTLE SUPPLEMENT Type B Medicated Feed (250 to 2000 g/ton)
- RUMENSIN® 80 Type B Medicated Feed for cattle maintained in confinement (100 to 1200 #ton)
- RUMENSIN® 80 Type B Medicated Feed for pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) (500 to 1200 g/ton)
- RUMENSIN® 80 Type B Medicated Feed for mature reproducing beef cows (on pasture or in dry lot) (500 to 1200 g/ton)

C. Specimen labeling (Blue Bird label) for Type C medicated feeds:

. RUMENSIN® 80 Type C Medicated Feed for cattle maintained in confinement (10 to 200 g/ton)

. RUMENSIN® 80 Type C Medicated Feed for pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) (25 to 400 g/ton)

. RUMENSIl@'80 Type C Medicated Feed for mature reproducing beef cows (on pasture or in dry lot) (25 to 400 g/ton)

. RUMENSIN® 80 Type C Medicated Calf Feed (1 O to 200 g/ton)

ELANCO

RUMENSIN® 80

Monensin Premix, USP ®

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

Do Not Feed Undiluted

Type A Medicated Article

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 cocadiosis 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, imperious gloves and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with water.**

For Veterinary Use Ordy
Store in a cool, dry place. Not to be used after date printed at top of bag.
Elanco Animal Health • A Division of Eli Lilly and Company
Indianapolis, IN 46285, U.S.A.
Questions or Comments **Call 1-800-428-4441**
Internet Address: **http://www.elanco.com**

Directions for Use

Read All Directions Carefully Before Mixing and Feeding

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

1. **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 Rumens in 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 200 mg per head per 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 head 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 the rate to provide 014 @0.42 mg per pound body weight per day depending upon severity of challenge up to a maximum of 360 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 few.

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

A. For improved feed efficiency when receiving supplemental feed. Feeding Directions: Feed 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 total ration. Feed (other than the Type C Medicated Feed containing Rumensin) can be restricted to 95% (of normal requirements) when 50 mg monensin activity is fed, and to 90% at 200 mg. Cow 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) or roughage such as silage, hay, ammoniated strew, hay or equivalent feedstuffs should be fed in order to meet NRC recommendations for mature reproducing beef cows to gain 025100475 pounds per head per day, Standing, dried winter range may not be adequate quality to result in improved efficiency when supplemented with Rumensin. During the first 5 days, pasture 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 the rate to provide 0.14 to 042 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 flint 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 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 the 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 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 level shown in Table 1. Dry Only - An Intermediate blending step should be performed to insure adequate mix.

B. Liquid Limitations

1 The supplement pH must be between 4.3-7.1.

2. Stored liquid Type B Medicated Feeds containing Rumensin: Recirculate or agitate liquid Type B Medicated Feeds even when cm Type B feed is used and immediately prior to use for no less than 10 minutes using no less than 10% 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 could be fatal to goats.

Table 1. MIXING DIRECTIONS

Amount of Rumensin 80 per ton		Monensin Activity in Medicated Feed	
lbs.	grams	grams/ton	g/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

BLUEBIRD COCCI PELLET
Rumensin® Type B Medicated Feed

DO NOT FEED UNDILUTED

For the prevention and control of coccidiosis in cattle caused by *Eimeria bovis* and *Eimeria zuernii.*

ACTIVE DRUG INGREDIENT

Monensin (as monensin premix)..... 300 to 2000 @on

GUARANTEED ANALYSIS

Nutritional Ingredients..... xx%

INGREDIENTS
As listed in AAFCO Handbook

MIXING DIRECTIONS

Thoroughly mix **30** to **200** pounds of this Type B Medicated Feed with 1970 to 1800 pounds of nonmedicated feed or feed ingredients to manufacture a Type C Medicated Feed containing g/ton__ (mg/lb). of monensin.

FEEDING DIRECTIONS

Feed to provide each animal 0.14 to 0.42 mg monensin per pound of body weight per **day** (depending on severity of challenge), up to a maximum of 360 mg monensin/hd/day for confined cattle; up to a maximum of **200** mg monensin/hd/day for pastured cattle. Maybe handfed or mixed into complete feed. IMPORTANT: During the first 5 days, cattle on pasture should receive no more than 100 mg monensin per day contained in not less than 1 pound of feed.

FEEDING CHART

Monensin Level **in Type C** Feed, **g/t (example)**	**Amount to feed per 100 lbs. bodyweight to provide 0.14 to 0.42 mg per pound** per **day**
30(1 5 mg/lb)	1 - 3 lbs.
60 (30 mg/lb)	0.5- 1.5 lbs.
90 (45 mg/lb)	0.33-1 lbs.
200 (100 mg/lb)	0.14-0.42 lbs.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

WARNING: A withdrawal period has not been established for monensin in pre-ruminating calves. Do not feed to calves to be processed for veal.

Manufactured by:

Expiration Date:_____ Lot No._____

draft 9/98

NET WEIGHT ON BAG OR BULK

BLUEBIRD MEDICATED **CATTLE** SUPPLEMENT
Rumensin ® Type B Medicated Feed

DO NOT FEED UNDILUTED

For the prevention and control of coccidiosis in cattle caused by *Eimeria bovis* and *Eimeria zuernii.*

ACTIVE DRUG INGREDIENT

Monensin (as monensin premix) ..... 250 to 2000 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients ..... xx%

INGREDIENTS
As listed in AAFCO Handbook

MIXING DIRECTIONS

Thoroughly mix 80 to 200 pounds of this Type B Medicated Feed with 1920 to 1800 pounds of nonmedicated feed or feed ingredients to manufacture a Type C Medicated Feed containing g / t (mg/lb) of monensin.

FEEDING DIRECTIONS

Feed to provide each animal 0.14 to 0.42 mg monensin per pound of body weight per day (depending upon severity of challenge), up to a maximum of 360 mg monensin/hd/day for confined cattle; up to 200 mg/hd/day for pastured cattle. May be handfed or mixed into complete feed. IMPORTANT During the first 5 days, cattle on pasture should receive no more than 100 mg per day contained in not less than 1 pound of feed.

FEEDING CHART

Monensin Level in Type C Feed (example)	**Amount to feed per 100 lbs. bodyweight to provide** 0.14 **to** 0.42 mg p**er** pound per day
30 (15 mg/lb)	1 - 3 lbs.
60 (30 mg/lb)	0.5- 1.5 lbs.
90 (45 mg/lb)	0.33-1 lbs.
200 (100 mg/lb)	0.14-0.42 lbs.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

WARNING: A withdrawal period has not been established for monensin in pre-ruminating calves. Do not feed to calves to be processed for veal.

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NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE B MEDICATED FEED

DO NOT FEED UNDILUTED

FEED TO CATTLE MAINTAINED IN CONFINEMENT

For the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.
For improved feed efficiency.

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . .100 to 1200 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . xx%

INGREDIENTS

As listed in AAFCO Handbook.

MIXING & FEEDING DIRECTIONS
(Example: 600 g/t Type B Medicated Feed)

Mix thoroughly the appropriate amount of Rumensin Type B medicated feed with grain and roughage to provide a Type C medicated feed as follows:

Monensin Level in Type C Medicated Feed g/t (mg/lb)	Amount of Type B Medicated Feed to make a ton of Type C Medicated Feed lbs/ton	Amount of Grain and/or Roughage lbs/ton
5 (2.5)	16.7	1983.3
10 (5)	33	1967
20 (lo)	67	1933
30 (15)	100	1900

1. **For coccidiosis prevention and control:** Feed 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of challenge, up to a maximum of 360 mg monensin/hd/day.

2. **For improved feed efficiency:** Feed the Type C Medicated Feed (5 to 30 g/t) continuously to cattle maintained in confinement to provide 50 to 360 mg monensin per head per day.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

MANUFACTURED BY:

Expiration Date: _____ Lot Number: _____

draft 9/98

NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE B MEDICATED FEED

DO NOT FEED UNDILUTED

FEED TO PASTURE CATTLE (SLAUGHTER, STOCKER, FEEDER, AND DAIRY AND BEEF REPLACEMENT HEIFERS)

For increased rate of weight gain; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuemii.*

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . .500 to 1200 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . xx%

INGREDIENTS

As listed in AAFCO Handbook

MIXING DIRECTIONS

Mix thoroughly 200 to 666.7 pounds of this type B Medicated Feed with 1800 to 1333.3 pounds of grain or roughage to make a Type C Medicated Feed containing _ g/t (mg/lb)_ o f monensin a s indicated below

Monensin Level in Type B Medicated Feed	Monensin Level in Type C Medicated Feed	Pounds of Type B Medicated Feed to make a ton of Type C Medicated Feed	Feeding Level of Type C Medicated Feed	Monensin Dose
g/ton	g/ton (mg/lb)	lbs/ton	lbs/hd/day	mg/hd/day
500	50 (25)	200.0	2-8	50-200
600	100 (50)	333.4	1-4	50-200
800	200 (1 00)	500.0	1-2	100-200
1000	300 (1 50)	600.0	1 -1.3	150-200
1200	400 (200)	666.6	1.0	200"

● Maximum Approved Level

FEEDING Directions

1. **For prevention and control of coccidiosis:** Feed the Type C Medicated Feed continuously to provide 0.14 to 0.42 mg monensin/lb BW per day, depending upon severity of challenge, up to a maximum of 200 mg monensin/hd/day.

2. **For increased rate of weight gain: Feed 50** to **200** mg monensin/hd/day

-OR-

After the 5th day, feed at the rate of 400 mg monensin/hd every other day in not less than 2 lbs. of feed.

IMPORTANT: During the first 5 days, cattle should receive no more than 100 mg monensin per day contained in not less than 1 lb. of feed.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

MANUFACTURED BY:

Expiration Date: _____ Lot Number_____

draft 9/98

NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE B MEDICATED FEED

DO NOT FEED UNDILUTED

FEED TO MATURE REPRODUCING BEEF COWS (ON PASTURE OR IN DRY LOT)

For improved feed efficiency when receiving supplemental feed; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . . . 5 00 to 1200 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . xx%

INGREDIENTS

As listed in AAFCO Handbook.

MIXING DIRECTIONS

Thoroughly mix pounds of this Type B Medicated Feed with pounds of grain and/or roughage to make a Type C Medicated Feed containing g/ton as indicated in the chart below.

Monensin Level in Type B Medicated Feed **g/ton**	**Amount of Type B Medicated Feed to make a ton of** Type C Medicated **Feed** **lbs./ton**	**Monensin Level in Type C Medicated Feed** **g/ton (mg/lb)**	**Recommended Feeding Level** **(lbs/hd/day)**	**Monensin Dose** **(mg/hd/day)**
500	200.0	50 (25)	2 - 8	50-200
600	333.4	100 (50)	1 - 4	50-200
800	500.0	200 (1 00)	1 - 2	100-200
1000	600.0	300 (1 50)	1 -1.3	150-200
1200	666.6	400" (200)	1.0	200*

● Maximum Approved Level

FEEDiNG Directions

For prevention and **control** of **coccidiosis:** Handfeed as indicated above to provide 0.14 to 0.42 mg **monensin/lb** body weight /day up to a maximum of 200 mg **monensin/hd/day,** or mix in the daily ration to provide not more than 200 mg per head per day.

For improved feed efficiency Feed 50 to 200 mg monensin/hd/day. Blend into a minimum of 1 lb. 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 is fed, and to 90?4$_0$ at 200 mg of **monensin.**

Cows on pasture or in dry **lot** must receive a minimum of 1 lb. of Type C Medicated Feed per head per day. Additionally, a minimum of 16**lbs. (air-dry** basis) or roughage such as **silage, haylage,** amrnoniated 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 **lbs/hd/day.** Standing, dried winter range forage may not be of adequate quality to result in improved efficiency when supplemented with **Rumensin.**

iMPORTANT: **During the** first *5* days, cattle on pasture should receive no more than 100 mg **monensin/day** contained in not iess than 1 **lb.** of feed.

CAUTIONS: **Do** not **allow** horses or other equines access to formulations **containing Rumensin.** ingestion of **Rumensin** by equines has been fatal. **Rumensin** medicated **cattle** feed is safe for use in **cattle only.** 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 feed **undiluted.** 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.

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NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE C MEDICATED FEED

FEED TO CATTLE MAINTAINED IN CONFINEMENT

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

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . . . .10 to 200 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . xx%

INGREDIENTS

As listed in AAFCO Handbook

MIXING & FEEDING DIRECTIONS

Handfeed or mix into complete feed and feed continuously to cattle to provide 0.14 to 0.42 mg monensin/lb. bodyweight, depending upon severity of challenge, up to a maximum of 360 mg monensin/hd/day.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

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NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE C MEDICATED FEED

FEED TO PASTURE CATTLE (SLAUGHTER, STOCKER, FEEDER, AND DAIRY AND BEEF REPLACEMENT HEIFERS)

For increased rate of weight gain; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii.*

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . .25 to 400 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . xx%

INGREDIENTS

As listed in AAFCO Handbook.

FEEDING DIRECTIONS

Feed the appropriate amount of Type C Medicated Feed to cattle on pasture to provide 50 to 200 mg monensin/hd/day. Mix thoroughly the appropriate amount of **Rumensin** with grain and roughage to provide a complete feed as follows:

Daily **Monensin** Dose mg/hd/day	**Monensin** Level in Type C Medicated Feed g/ton (mg/lb)	Recommended Feeding Level (lbs/hd/day)
50	25 (12.5)	4
60	30 (15)	4
50	50 (25)	2
60	60 (30)	2
100	100 (50)	2
200	200 (1 00)	2
150	300 (1 50)	1
200'	400" (200)	1

•Maximum Approved Level

FEEDING DIRECTIONS

For coccidiosis prevention and control: Handfeed at the **rate of 0.14 to 0.42** mg **monensin/lb/** body weight per day, depending upon severity of challenge, up to 200 mg monensin/hd/day.

For increased rate of weight gain:

1. Feed at the rate of not less than 50 nor more than 200 mg **monensin/hd/day** in not less than 1 lb. of medicated feed;

-OR-

2. After the 5th day, feed at the rate of 400 mg **monensin/hd/day** every other day in not less than 2 **lbs.** of feed.

IMPORTANT During the first 5 days, cattle should receive no more than 100 mg **monensin/day** contained in not less than 1 lb. of feed.

CAUTIONS: **Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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.

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RUMENSIN® TYPE C MEDICATED FEED

FEED TO MATURE REPRODUCING BEEF COWS (ON PASTURE OR IN DRY LOT)

For improved feed efficiency when receiving supplemental feed; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii.*

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . .25 to 400 /ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . .xx%

INGREDIENTS

As listed in AAFCO Handbook.

FEEDING CHART

Level of Monensin in Type C Medicated Feed (g/ton)	Recommended Feeding Levei (lbs/hd/day)	Monensin Dose (mg/hd/day)
25(1 2.5 mg/lb)	4	50
30 (15 mg/lb)	4	60
50 (25 mg/lb)	2	50
60 (30 mg/lb)	2	60
100 (50 mg/lb)	2	100
200 (100 mg/lb)	2	200
300 (150 mg/lb)	1	150
400' (200 mg/lb)	1	200"

*Maximum Approved **Level**

FEEDING Directions

For coccidiosis prevention and control: Handfeed at the rate of 0.14 to 0.42 mg monensin/lb/ BW per day, depending upon severity of challenge, up to **200** mg monensin/hd/day.

For improved feed efficiency Handfeed or mix 50 to 200 mg monensin/hd/day into the total ration. Feed undiluted or blend with an appropriate amount of ground feed according to the above mixing directions. Feed (other than the Type C Medicated Feed containing Rumensin) can be restricted to **95%** (of normal requirements) when 50 mg of monensin is fed, and to **90%** at 200 mg monensin.

Cows on pasture or in dry lot must receive a minimum of 1 lb. of Type C Medicated Feed per head per day. Additionally, a minimum of 16 lbs. (air-dry basis) or 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 lbs./hd/day. Standing, dried winter range forage may not be of adequate quality to result in improved efficiency when supplemented with Rumensin.

iMPORTANT During the first 5 days, cattle on pasture should receive no more than 100 mg monensin/day contained in not less than 1 lb. of feed.

CAUTIONS: Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal. Rumensin medicated cattle feed is safe for use in cattle only. 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 feed undiluted. 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 rows. Do not feed to lactating goats.

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NET WEIGHT ON BAG OR BULK

RUMENSIN® TYPE C MEDICATED CALF FEED

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

ACTIVE DRUG INGREDIENT

Monensin (asmonensin premix) . . . .10 t0200 g/ton

GUARANTEED ANALYSIS

Nutritional Ingredients . . . . . xx%

INGREDIENTS
As listed in AAFCO Handbook

MIXING & FEEDING DIRECTIONS

Hand feed continuously to calvestotxovide0.14 tq 1.00 mg monensin/lb. bodyweight, depending upon severity of challenge, up to a maximum of 200 mg monensin/hd/day.

Example for 30 g monensin per ton complete feed:

Calf Weight	Feed par day (lb)		Monensin Intake (mg/day)	
(lbs)	Mln	Max	Min	Max
100	0.93	*ad libitum*	14	60'
200	1.86	*ad libitum*	28	1 20*
300	2.80	*ad libitum*	42	180*
400	3.73	13.3	56	200

"Limited by appetite, assumed to be not more than 4% of body weight

Example for 200 g monensin per ton supplement:

Calf Weight	Feed per day (lb)		Mg monensin per day	
(lb)	Min	Max	Min	Max
100	0.14	1	14	100
200	0.28	2	28	200
300	0.42	2	42	200
400	0.56	2	56	200

CAUTIONS: **Do not allow horses or other equines access to formulations containing Rumensin. Ingestion of Rumensin by equines has been fatal.** Rumensin **medicated cattle feed is safe for** use in cattle only. 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. Da not feed undiluted. 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.**

WARNINGS: **A withdrawal** period has not been established for monensin in pre-runimating calves. Do not feed to calves to be processed for veal.

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