

Approval Date: NOV 18 2005

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 095-735

Monensin Sodium (RUMENSIN 80)

**Type A Medicated Article
for Beef Cattle**

For increased rate of weight gain; for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

This supplement provides for a change in the species class from pasture cattle (stocker and feeder cattle and dairy and beef replacement heifers) to growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

Sponsored By:

**Elanco Animal Health
A Division of Eli Lilly & Co.
Lilly Corporate Center
Indianapolis, IN 46285**

2005-95-735

FQ15 1

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FREEDOM OF INFORMATION SUMMARY

RUMENSIN 80

Type A Medicated Article for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers)

1. GENERAL INFORMATION:

- a. File Number: NADA 095-735
- b. Sponsor: Elanco Animal Health
A Division of Eli Lilly & Co.
Lilly Corporate Center
Indianapolis, IN 46285
Drug Labeler Code: 000986
- c. Established Name: Monensin sodium
- d. Proprietary Name: RUMENSIN 80
- e. Dosage Form: Type A Medicated Article
- f. How Supplied: 50 lb bag
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 80 grams per pound (176 g/kg)
- i. Route of Administration: Oral in feed
- j. Species/Class: Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers)
- k. Recommended Dosage: For increased rate of weight gain:
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 concentration 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.

Prevention and control of coccidiosis due to
Eimeria bovis and *Eimeria zuernii*:

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. The monensin concentration in Type C Medicated Feed must be between 25 and 400 g/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.

l. Pharmacological Category:

Ionophore

m. Indications:

For increased rate of weight gain; for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

n. Effect of Supplement:

This supplement provides for a change in the species class from pasture cattle (stocker and feeder cattle and dairy and beef replacement heifers) to growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

2. EFFECTIVENESS:

a. Dosage Characterization

The dosage for growing cattle fed on pasture or in a drylot was characterized in nine pasture dose titration trials and three greenchop (drylot) dose titration trials in the Freedom on Information (FOI) Summary for the supplemental approval for monensin in pasture cattle (slaughter, stocker, and feeder) (NADA 095735) approved July 28, 1978 (FR 32749, Vol: 43, No. 146, July 28, 1978).

b. Substantial Evidence

The data presented serve as justification for changing the Code of Federal Regulations (CFR) Title 21 §558.355(f)(3)(iii)(b) to more accurately reflect the feeding and management systems utilized in the studies that were the subject of the original approval. The data demonstrated a statistically significant weight gain advantage to growing cattle whether they were fed on pasture or in a drylot.

A. GROWING CATTLE (INCLUDING REPLACEMENT HEIFERS) ON PASTURE

Eleven trials (T1F067839, T1F187834, T1F207848, T1F307853, T1F387568, T1F207630, T1F367767, T1F487435, T1F427824, T1F4876A3, and T1F407804) were submitted on December 16, 1980, supporting the indication for increased rate of weight gain in replacement heifers on pasture (21 CFR §558.355(f)(3)(iii)). Supplements were fed at rates of 1 lb/head/day or mixed into a supplemental ration to deliver 200 mg monensin/head/day. These trials are summarized in Table 1.

Trial T1F407804 measured the effect of monensin on reproduction efficiency and weight change in first-calf replacement beef heifers on pasture. In the remaining 10 trials, heifers were maintained on pasture or in dirt or concrete lots. In trials T1F067839 and T1F187834, beef heifers were maintained on pasture. In trial T1F067839, supplemental barley was either hand-fed or offered free-choice in a self-feeder. In that same trial, some of the pastures were over-grazed, thus requiring alfalfa cubes to be fed for 75 of the 105 days. In trial T1F187834, corn was fed (*ad libitum* to one group) to supplement grazing in two of the treatment groups.

In three trials (T1F207848, T1F307853, and T1F387568), beef heifers were confined in dirt lots. These animals were fed similar rations consisting predominantly of hay, oats, corn, corn silage, and/or sorghum milo silage.

Three trials, (T1F207630, dairy heifers; T1F367767, dairy heifers; and T1F487435 beef heifers) utilized a combination of both pasture and dirt lots. The feeding program in those trials included hay, milo, corn silage and range cubes in addition to bromegrass, and wheat-oat-rye grass pastures.

In one trial (T1F427824) dairy heifers were housed on concrete in pens and fed ensiled hay and corn and supplemented with ground corn and trace minerals.

In 1 trial, (T1F4876A3), beef heifers were fed alfalfa hay and concentrate with three pens of heifers confined to dirt lots and the other three pens on concrete.

In summary, Table 1 shows that heifers fed 200 mg monensin/day grew an average of 0.13 lb/day faster ($P < 0.001$) than controls. It also shows that heifers were maintained either on pasture, in confinement or on a combination of pasture plus confinement during the trials.

Table 1 Average Daily Gain (lb) of Heifers Supplemented with Monensin

Trial Number	Pasture	Dirt	Concrete	Monensin Intake (mg/head/day)		Advantage
				0	200	
T1F067839	X			1.17	1.41	+0.24
T1F187834	X			1.85	2.10	+0.25
T1F207848		X		1.40	1.48	+0.08
T1F307853		X		1.08	1.45	+0.37
T1F387568		X		1.36	1.49	+0.13
T1F207630	X	X		1.58	1.71	+0.31

CA-251	Steers			X	1.09	1.29	+0.20
T1F3876D4	Heifers			X	1.57	1.68	+0.11
306-T1F-5-30	Heifers			X	1.95	2.04	+0.09
306-739-3-1	Heifers		X		2.35	2.44	+0.09
306-739-3-12 ^a	Mixed				1.51	1.62	+0.11
306-739-4-29	Heifers			X	1.46	1.57	+0.11
306-739-4-8	Steers		X		1.14	1.36	+0.22
Average					1.43	1.57	+0.14
LS Treatment Means ^b					1.57	1.69	+0.12

LS = least squares

^a The report for this study did not indicate whether pasture or dirt or concrete lots were used.

^b Adjusted for experiment and group within experiment effects

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The product's target animal safety in pasture cattle (slaughter, stocker, and feeder) has been established in the Freedom of Information (FOI) Summary for the new animal drug application for RUMENSIN (NADA 095735) dated July 28, 1978 (FR 32749, Vol: 43, No. 146, July 28, 1978). The product's target animal safety in pasture cattle (dairy and beef replacement heifers) has been established in the Freedom of Information (FOI) Summary for the new animal drug application for RUMENSIN (NADA 095735) dated September 28, 1983 (FR 44204, Vol: 48, No. 189, September 28, 1983).

4. HUMAN SAFETY:

No new target animal safety data are required for the approval of this supplement. The product's target animal safety in beef cattle has been established in the Freedom of Information (FOI) Summary for the new animal drug application for RUMENSIN (NADA 095735) in cattle fed in confinement for slaughter dated (FR 58289-58290, Vol:40, No. 242, December 16, 1975).

5. AGENCY CONCLUSIONS:

The data submitted in support of this 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 monensin sodium fed 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 for increased rate of weight gain or fed 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 for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) is safe and effective for the claims indicated in section 1 of this FOI Summary.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Pursuant to 21 CFR 514.106 (b)(2)(vi), this supplemental NADA approval is regarded as a Category II supplemental change which required a reevaluation of safety and efficacy data in the parent NADA.

The drug is to be fed in Type C medicated feeds in accordance with section 1 of the FOI Summary and the Blue Bird labeling that is attached to this document.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions provide detailed instruction in plain language. The drug product is not a controlled substance. Thus, the drug product is assigned OTC status, and the labeling is adequate for the intended use.

No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

- Type A Medicated Article
- Type B Blue Bird Label
- Type C Blue Bird Label
- Type C Free Choice Mineral Granules Label

Freedom of Information Summary
N-095735-C-0289, RUMENSIN 80
Page 8

cc: Courtesy copy for sponsor
HFV-199, NADA 095-735 C-0289, S-0292 Orig
HFV-1, Special Mailing List
HFV-12, FOI Staff
HFV-107, Reserve Copy
HFV-104, Green Book
HFV-120, Labeling Project
HFV-216, Surveillance Copy
HFV-230, Compliance Copy
HFA-305, Division of Dockets Management

PARyan/Swine and Poultry Drugs Team (HFV-128): November 8, 2005

ELANCO*

AF 0480-50B

For Animal Feed Only

Rumensin® 80

Monensin Granulated, USP

(The diagonal color bar will be added with an "*" added to the bottom right hand corner)

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

Type A Medicated Article

Do Not Feed Undiluted

- Feedlot Cattle:**
- For improved feed efficiency (cattle fed in confinement for slaughter).
 - For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.
- Dairy Cows:**
- For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).
- Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers):**
- For increased rate of weight gain.
 - For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.
- Mature Reproducing Beef Cows:**
- For improved feed efficiency when receiving supplemental feed.
 - For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.
- Goats:**
- For the prevention of coccidiosis caused by *Eimeria crandallis*, *Eimeria christensenii*, and *Eimeria ninakohlyakimovae* in goats maintained in confinement.
- Calves (excluding veal calves):**
- For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

CAUTION: Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. — Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin 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 monensin recommended in the feeding directions as reduced average daily gains may result. Do not feed to lactating goats. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

YOU MAY NOTICE:

- Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment.
- Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed.
- Increased incidence and treatment of cystic ovaries and metritis in dairy cows fed monensin.

- Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin.
Have a comprehensive and ongoing nutritional, reproductive and herd health program in place when feeding monensin to dairy cows.

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

To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Back of Bag

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:

- 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 per head per day.
- For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.** Feeding Directions: Feed continuously (10 to 30 g/ton) to provide 0.14 to 0.42 mg per pound of body weight per day, depending upon severity of challenge, up to a maximum of 360 mg of monensin per head per day.

II. Dairy Cows:

- For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).** Feeding Directions: Feed continuously to dry and lactating dairy cows a total mixed ration ("complete feed") containing 11 to 22 g/ton monensin on a 100% dry matter basis (Table 2).

III. Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers):

- 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 concentration in the 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.
- 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. The monensin concentration in Type C Medicated Feed must be between 25 and 400 g/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.

C. Free-Choice (Self-Fed) Medicated Feeds.

All free-choice medicated feeds must provide not less than 50 nor more than 200 mg monensin per head per day. (1) Free-choice medicated feeds manufactured from a published formula and/or specifications do not require a medicated feed mill license. (2) Other manufacturers of Type C free-choice feeds with a proprietary formula and/or specifications require an FDA approved Medicated Feed Mill License.

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

A. For improved feed efficiency when receiving supplemental feed. Feeding

Directions: Feed continuously at a rate of 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 of 0.14 to 0.42 mg per pound of 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.

V. Goats:

A. For prevention of coccidiosis caused by *Eimeria crandallis*, *Eimeria christensenii* and *Eimeria ninakohlyakimovae*. Feeding Directions: Feed complete feed (20 g/ton) continuously to goats as the sole ration. Feed only to goats maintained in confinement.

VI. 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. The monensin concentration in Type C Medicated Feed must be between 10 and 200 g/ton.

VII. 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

1. The supplement pH must be between 4.3 – 7.1.
2. Stored liquid Type B Medicated Feeds containing Rumensin: For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. • For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

CAUTION: Inadequate mixing (recirculation or agitation) of monensin Liquid Type B or C Medicated Feeds has resulted in increased monensin concentration which has been fatal to cattle and could be fatal to goats. • If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing.

Directions for Use: Read All Directions Carefully Before Mixing and Feeding

Table 1. Mixing Directions for Feedlot Cattle Feeds

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

^a 90% dry matter basis

Table 2: Mixing Directions for Dairy Cow Total Mixed Rations^a

Amount of Rumensin 80 to make a Type B

Amount of Type B to add to total mixed ration, lb

Desired monensin concentration	Amount of Rumensin 80 needed per ton of Type B, lb	Dry matter of total mixed ration, %	Desired monensin concentration, g/ton in total mixed ration ^c		
			11	15	22
500	6.25	55	24.20	33.00	48.40
		60	26.40	36.00	52.80
		65	28.60	39.00	57.20
1,440	18	55	8.40	11.46	16.81
		60	9.17	12.50	18.33
		65	9.93	13.54	19.86
4,500	56.25	55	2.7	3.7	5.4
		60	2.9	4.0	5.9
		65	3.2	4.3	6.4
8,000	100	55	1.5	2.1	3.0
		60	1.7	2.3	3.3
		65	1.8	2.4	3.6

^a Amount of Type B needed to produce the total mixed ration with desired level of monensin is as follows:
 $((\text{Desired level of monensin in total mixed ration g/ton}) \times (\% \text{ dry matter of total mixed ration}) / \text{g/ton of monensin in Type B}) \times 2000$

^b It is recommended that Type B feeds containing more than 1440 g/ton be further diluted before mixing into the total mixed ration. An example of further dilution would be a ratio of 1:10 of Type B Medicated Feed:Unmedicated Feed.

^c 100% dry matter basis.

(Printed with Soy Ink Logo)

(Take Time Eye Logo)

II-DEC-04

NET WEIGHT ON BAG OR BULK

MONENSIN TYPE B MEDICATED CATTLE FEED

DO NOT FEED UNDILUTED

For increased rate of weight gain; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

ACTIVE DRUG INGREDIENT

Monensin sodium 401 to 80,000 g/ton*

GUARANTEED ANALYSIS

Crude Protein, not less than.....	_____	%
Non-Protein Nitrogen (NPN) ¹ , not more than.....	_____	%
Crude Fat, not less than.....	_____	%
Crude Fiber, not more than.....	_____	%
Calcium, not less than.....	_____	%
Calcium, not more than.....	_____	%
Phosphorus, not less than.....	_____	%
Salt ² , not less than.....	_____	%
Salt ² , not more than.....	_____	%
Sodium ³ , not less than.....	_____	%
Sodium ³ , not more than.....	_____	%
Potassium, not less than.....	_____	%
Vitamin A ^{2,4} , not less than.....	_____	I.U./lb

¹When added.

²If added.

³Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

⁴Other than precursors of Vitamin A.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

MIXING DIRECTIONS

Thoroughly mix monensin Type B medicated feed into one ton of grain or roughage according to the table below to obtain the correct concentration in the Type C medicated feed (25 to 400 g/ton). Use only the portion of the table below that is applicable to the concentration of monensin in the Type B medicated feed you manufacture.

Amount of Monensin in Type B Medicated Feed	Monensin Desired in Type C Medicated Feed	Pounds of Type B Medicated Feed to make a ton of Type C Medicated Feed*
g/ton	g/ton (mg/lb)	lbs/ton
500	25 (12.5)	100
500	400 (200)	1600
1000	25 (12.5)	50
1000	400 (200)	800
5000	25 (12.5)	10
5000	400 (200)	160

* Amount of Type B needed to produce the ration with desired level of monensin is as follows:

$$\frac{\text{Desired level of monensin in complete feed}}{\text{monensin grams per ton in Type B}} \times 2000$$

CAUTIONS

Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin 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 monensin recommended in the feeding directions as reduced average daily gains may result. Do not feed to lactating goats. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

Manufactured By

**Blue Bird Feed Mill
Anytown, USA 12345**

*Final printed label on formulated Type B medicated feed must bear a single drug concentration

NET WEIGHT ON BAG OR BULK

MONENSIN TYPE C MEDICATED CATTLE FEED

For increased rate of weight gain; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

ACTIVE DRUG INGREDIENT

Monensin sodium 25 to 400 g/ton*

GUARANTEED ANALYSIS

Crude Protein, not less than.....	_____	%
Non-Protein Nitrogen (NPN) ¹ , not more than.....	_____	%
Crude Fat, not less than.....	_____	%
Crude Fiber, not more than.....	_____	%
Calcium, not less than.....	_____	%
Calcium, not more than.....	_____	%
Phosphorus, not less than.....	_____	%
Salt ² , not less than.....	_____	%
Salt ² , not more than.....	_____	%
Sodium ³ , not less than.....	_____	%
Sodium ³ , not more than.....	_____	%
Potassium, not less than.....	_____	%
Vitamin A ^{2,4} , not less than.....	_____	I.U./lb

¹When added.

²If added.

³Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

⁴Other than precursors of Vitamin A.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed the appropriate amount of Type C Medicated Feed to cattle to provide 50 to 200 mg monensin/hd/day. During the first 5 days, cattle should receive no more than 100 mg monensin/day contained in not less than 1 lb. of feed.

For increased rate of weight gain: Feed at a rate of not less than 50 nor more than 200 mg monensin/hd/day in not less than 1 lb. of medicated feed;

-OR-

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.

For coccidiosis prevention and control: Feed 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.

Desired Intake of Monensin	Concentration of Monensin In Type C Medicated Feed	Recommended Feeding Level
mg/hd/day	g/ton (mg/lb)	(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 (100)	2
150	300 (150)	1
200*	400* (200)	1

*Maximum Approved Level

CAUTIONS

Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Do not exceed the levels of monensin recommended in the feeding directions as reduced average daily gains may result. Do not feed to lactating goats. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing.

WARNING

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

Manufactured By

Blue Bird Feed Mill
Anytown, USA 12345

Expiration Date: Type C cattle feeds containing 30 g/ton or less of monensin shall bear an expiration date of 30 days after date of manufacture.

* Final printed label on formulated Type C medicated feed must bear a single drug concentration.

NET WEIGHT ON BAG OR BULK

FREE CHOICE MONENSIN MINERAL GRANULES TYPE C MEDICATED FEED

For increased rate of weight gain; For prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

ACTIVE DRUG INGREDIENT

Monensin sodium.....1,620 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 growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers). 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 for cattle on pasture is dependent on good pasture conditions.

CAUTIONS

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. 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 or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle feeds are safe for use in cattle only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions as reduced average daily gains may result. Do not feed to lactating goats.

WARNING

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

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Lot No. _____