

Approval Date: DEC 15 2005

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 095-735

Monensin Sodium (RUMENSIN 80)

**Type A Medicated Article
for Dairy Cattle**

For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

This supplement to the NADA provides for use of RUMENSIN 80 in dairy cows in component feeding systems (including top dress).

Sponsored By:

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

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FREEDOM OF INFORMATION SUMMARY

RUMENSIN 80 Type A Medicated Article for Dairy Cattle

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: Monensin sodium – 80 grams per pound (176 g/kg)
- i. Route of Administration: Oral in feed
- j. Species/Class: Dairy Cows
- k. Recommended Dosage: Component Feeding Systems (including top dress): Feed continuously to dry and lactating dairy cows a Type C medicated feed containing 11 to 400 g/ton monensin. The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. This provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin on a 100% dry matter basis.

- l. Pharmacological Category: Ionophore
- m. Indications: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).
- n. Effect of Supplement: This supplement to the NADA provides for use of RUMENSIN 80 in dairy cows in component feeding systems (including top dress).

2. **EFFECTIVENESS:**

a. Dosage Characterization

Dose characterization was performed as part of substantial evidence (see item 2.b below).

b. Substantial Evidence

Data described in the Freedom of Information (FOI) Summary for the parent new animal drug application for monensin in dairy cows approved October 28, 2004 (NADA 095-735), were used to establish effectiveness of monensin when used in component feeding systems (including top dress) for dairy cows. Data from this study, conducted with dairy cows fed monensin in total mixed rations (TMR), utilized daily dry matter intake (DMI) of individual cows (summarized on a weekly basis in lactation and dry periods), to determine daily monensin intake (mg/head/day). Cows were fed TMR containing 0, 8, 16, and 24 ppm monensin (100% dry matter basis). The approved range of monensin concentrations in TMR from the approval of October 28, 2004, was 12 to 24 ppm. Twelve (12) ppm was established as the low end of the approved range by use of non-overlapping confidence interval methods, see FOI Summary of October 28, 2004, approval. When monensin was expressed on a g/ton basis (100% dry matter basis), the tested doses were 0, 7, 15, and 22 g/ton, and the approved range was 11 to 22 g/ton. For purposes of data presentation in the current FOI Summary, monensin concentrations are expressed in ppm.

Monensin intakes were calculated by multiplying the mean daily DMI for each animal for each week of the study by the monensin dose. Data from the 16 and 24 ppm treatment groups were used to establish ranges in mg/head/day monensin intake. These two monensin concentrations were within the approved range of monensin concentrations, and DMI were not available at 12 ppm.

The measure of variability of monensin intakes employed was ± 2 standard deviations from the mean for the 16 and 24 ppm doses, and the ranges were calculated as follows:

1. Calculate the arithmetic mean (M) and standard deviation (STD) for each treatment group (16 and 24 ppm) from the average daily DMI during each week of the period for each animal.
2. Compute "Confidence Limits" (the plus/minus 2-standard deviation limits) with unit kg/head/day of DMI.
 $M_n \pm 2*STD_n$ for dose "n" ppm.
3. Compute "Confidence Limits" with unit mg/head/day of monensin.
 $n*M_n \pm n*2*STD_n$ for dose n ppm.
4. The range of the monensin intake is from $(16*M_{16} - 16*2*STD_{16})$ to $(24*M_{24} + 24*2*STD_{24})$.

For calculating the ranges during lactation, DMI data were used for the standardized lactation period of the first on-study lactation (1 to 308 days in milk (DIM); see FOI Summary of October 28, 2004). For calculating ranges during the dry period, data were used from the first eight weeks following the first on-study lactation.

Results for the lactating cows are summarized in Table 2.1.

| Variable | Monensin (ppm) | Average | STD | -2STD | +2STD |
|-------------------------------|----------------|---------|------|-------|-------|
| DMI (kg/head/day) | 16 | 19.7 | 4.1 | 11.6 | 27.9 |
| | 24 | 19.5 | 4.0 | 11.6 | 27.4 |
| Monensin Intake (mg/head/day) | 16 | 315.6 | 65.3 | 185.0 | 446.3 |
| | 24 | 468.9 | 94.9 | 279.1 | 658.7 |
| STD – Standard Deviation | | | | | |

During lactation, the range of monensin intakes from -2 STD for the 16 ppm dose to +2 STD for the 24 ppm dose was 185 to 659 mg/head/day.

Results for dry cows are summarized in Table 2.2.

| Variable | Monensin (ppm) | Average | STD | -2STD | +2STD |
|----------|----------------|---------|-----|-------|-------|
| DMI | 16 | 12.6 | 2.7 | 7.2 | 17.9 |

| | | | | | |
|----------------------------------|----|-------|------|-------|-------|
| (kg/head/day) | 24 | 12.0 | 2.6 | 6.8 | 17.1 |
| Monensin Intake (mg/head/day) | 16 | 200.8 | 42.6 | 115.6 | 286.0 |
| | 24 | 286.8 | 61.6 | 163.6 | 410.0 |
| STD – Standard Deviation | | | | | |

The range of monensin intakes from -2 STD for the 16ppm average to +2 STD for the 24ppm average was 116 to 410 mg/head/day.

The ranges in mg/head/day doses of monensin to dry and lactating cows necessitate a broad range of g/ton monensin concentrations in the Type C medicated feed for component feeding systems (including top dress). To this end, the sponsor proposed a range in monensin concentrations of 11 to 400 g/ton (as fed) in the Type C medicated feed for component feeding systems (including top dress). This proposal is supported by 1) U.S. approval for the use of Type C medicated feeds up to 400 g/ton for growing cattle (pasture and dry lot); and 2) ancillary studies supporting safe use in dairy cows with monensin concentrations in feed for component feeding and top dress of up to 450 ppm or approximately 400 g/ton (Van der Werf et al., 1998; Phipps et al., 2000). Therefore, the sponsor's proposal for the 11 to 400 g/ton monensin concentrations in the Type C medicated feed for component feeding systems (including top dress) is acceptable.

Given the above information, the approved label contains the following statement:

"Component Feeding Systems (including top dress): Feed continuously to dry and lactating dairy cows a Type C medicated feed containing 11 to 400 g/ton monensin. The Type C medicated feed must be fed in a minimum of 1 pound of feed per cow per day (Table 3) to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. This provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin on a 100% dry matter basis."

References:

J.H.J. Van der Werf, L.J. Jonker and J.K. Oldenbroek. 1998. Effect of monensin on milk production by Holstein and Jersey cows. J. Dairy Sci. 81:427-433.

Phipps, R.H., J.I.D. Wilkinson, L.J. Jonker, M. Tarrant, A.K. Jones and A. Hodge. 2000. Effect of monensin on milk production of Holstein-Friesian dairy cows. J. Dairy Sci. 83:2789-2794.

3. TARGET ANIMAL SAFETY:

Target animal safety was established in the parent new animal drug application for monensin in dairy cows (See FOI Summary of the approval of October 28, 2004).

4. HUMAN SAFETY:

This supplemental application is for an alternative feeding method for the use of RUMENSIN 80 Type A Medicated Article (monensin sodium) in dairy cattle. No additional human food safety studies were required to support this supplemental approval because FDA determined that the human food safety information was available in the parent new animal drug application for monensin in dairy cows (See FOI Summary of the approval of October 28, 2004).

A. Toxicology:

An ADI for monensin of 12.5 micrograms per kilogram of body weight is codified for monensin (21 CFR 556.420).

Safe concentrations of 1.5, 3.0, 4.5, and 6.0 ppm were established for muscle, liver, kidney, and fat of cattle, respectively. The safe concentration of monensin in milk is 200 ppb.

B. Residue Chemistry

1. Residue Chemistry Studies

No additional residue chemistry studies were required for this supplemental approval. The residue study previously submitted to support the use of monensin in dairy cattle under NADA 095-735 reveals that the total residues in the edible tissues and milk at practical zero withdrawal were far below the safe concentrations when the cattle were dosed at 36g/ton. Therefore, FDA concluded that this alternative feeding method for the use of RUMENSIN 80 Type A Medicated Article (monensin sodium) in dairy cattle will not result in total residue concentrations in the tissues and milk of treated dairy cattle above the safe concentrations at the approved zero withdrawal.

2. Marker Residue and Target Tissue

The marker residue for monensin is parent monensin. A specific target tissue is not identified.

3. Tolerance for the Marker Residue

The codified tolerance for monensin in the edible tissues of cattle is 0.05 ppm (21 CFR 556.420). Milk tolerance for monensin is not required.

4. Withdrawal Period

Neither a preslaughter withdrawal period nor a milk discard period is required for the use of monensin in dairy cows.

C. Microbial Food Safety

The Agency has considered the proposed supplement to allow top-dress or component feeding of monensin (RUMENSIN 80) to dairy cattle, and determined that a hazard (characterized as zoonotic, pathogenic bacteria of public health concern in or on dairy cattle treated with monensin, and resistant to monensin or other human use antimicrobials as a result of exposure to monensin) is not of a magnitude that warrants further microbial food safety assessment at this time.

D. Analytical Method for Residues:

The requirement for a regulatory determinative method has been waived. However, the determinative HPLC method used to support the original monensin sodium applications is available from the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

E. User Safety Concerns:

User safety concerns associated with the effects of accidental inhalation or direct contact have been satisfactorily addressed by establishing label warnings. The bags of Type A medicated article, Type B medicated feed, and Type C medicated feed contain the following 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.

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 continuously as a component or top dress to dry and lactating dairy cows in a total diet containing 11 to 400 g/ton monensin, (185 to 660 mg/head/day to lactating or 115 to 410 mg/head/day to dry cows in a minimum of 1 lb of feed) is safe and effective for the claim indicated in section 1 of this FOI Summary. Component feeding (including top dress) in this manner provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin (100% dry matter basis), the conditions provided for in the parent new animal drug approval for RUMENSIN 80 (NADA 095735) in dairy cows dated October 28, 2004.

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)(i), this supplemental NADA approval is regarded as a Category II supplemental change which did require a reevaluation of safety and efficacy data in the parent NADA for dairy cattle.

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.

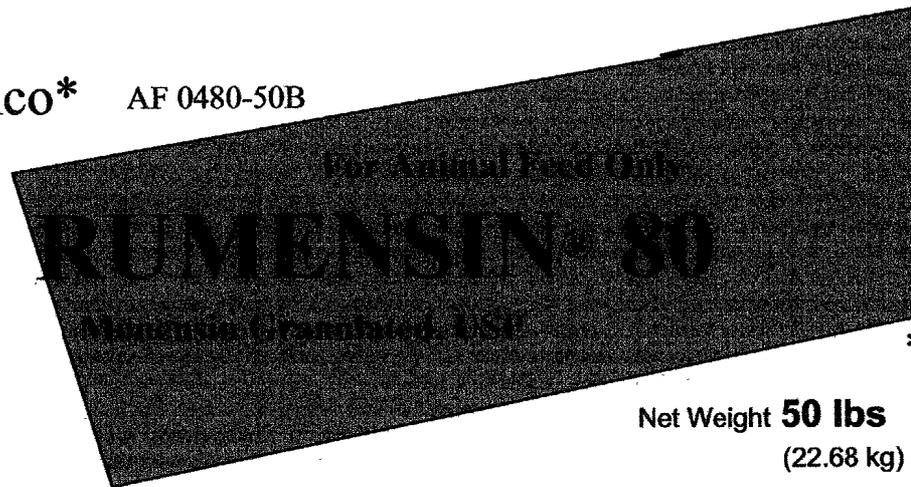
No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

RUMENSIN 80 Type A Medicated Article Label
Monensin Type B Dry Dairy Cattle Medicated Feed Label
Monensin Type B Liquid Dairy Cattle Medicated Feed Label
Monensin Type C Dairy Cattle Medicated Feed Label For Component Feeding System
(Including Top Dress)
Monensin Type C Dairy Cattle Medicated Feed Label For Total Mixed Rations

Elanco* AF 0480-50B



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*.

Dairy Cows: A. 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 and 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 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

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 per head per day.
- B. 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:

- A. For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).**
Feeding Directions:
Total Mixed Rations ("complete feed"): 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).
Component Feeding Systems (including top dress): Feed continuously to dry and lactating dairy cows a Type C Medicated Feed containing 11 to 400 g/ton monensin (Table 3). The Type C Medicated Feed must be fed in a minimum of 1 pound of feed per cow per day to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. This provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin on a 100% dry matter basis.

Directions for use, continued

III. Growing cattle on pasture or in dry lot (stocker and feeder and 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 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.
- 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. 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 christenseni* 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 ensure 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 |

^a90% dry matter basis

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

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^b | Amount of Rumensin 80 needed per ton of Type B, lb ^c | Dry matter of TMR, % | Desired monensin concentration, g/ton in TMR ^d | | |
|---|---|----------------------|---|-------|-------|
| | | | 11 | 15 | 22 |
| | | | lb of Type B (as-fed) needed per ton of TMR | | |
| 500 | 6.25 | 50 | 22.00 | 30.00 | 44.00 |
| | | 60 | 26.40 | 36.00 | 52.80 |
| 1440 | 18 | 50 | 7.64 | 10.42 | 15.28 |
| | | 60 | 9.17 | 12.50 | 18.33 |
| 8,000 | 100 | 50 | 1.5 | 2.1 | 3.0 |
| | | 60 | 1.7 | 2.3 | 3.3 |

^a Amount of Type B (as-fed basis) needed to produce the TMR with desired level of monensin is as follows:

$$\frac{((\text{Desired level of monensin in TMR g/ton}) \times (\% \text{ dry matter of TMR}) / (\text{g/ton of monensin in Type B})) \times 2000}{}$$

Example Diet: Desire 11 g/ton monensin in TMR (dry matter basis), TMR contains 50% dry matter, & Type B contains 500 g/ton of monensin.

Example Solution: $((11 \text{ g/ton}) \times (0.50 \text{ dry matter of TMR}) / 500 \text{ g/ton monensin in Type B}) \times 2000 = 22 \text{ lb of Type B needed per ton of TMR}$

^b It is recommended that Type B feeds containing more than 1440 g/ton be further diluted before mixing into the TMR.

An example of further dilution would be a ratio of 1:10 of Type B Medicated Feed:Unmedicated Feed.

^c (Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: $500 \text{ g/ton} / 80 \text{ g/lb} = 6.25 \text{ lb Rumensin 80 per ton of Type B}$

^d 100% dry matter basis

Table 3: Mixing Directions for Dairy Cows in Component Feeding Systems (Including Top Dress)^a

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^b | Amount of Rumensin 80 needed per ton of Type B, lb ^c | Desired Monensin Concentration, g/ton in Component Feed | | |
|--|---|---|--------|---------|
| | | 50 | 200 | 400 |
| | | lb of Type B (as-fed) needed per ton of component feed | | |
| 500 | 6.25 | 200.00 | 800.00 | 1600.00 |
| 1700 | 21.25 | 58.82 | 235.29 | 470.59 |
| 4000 | 50 | 25.00 | 100.00 | 200.00 |
| 8000 | 100 | 12.50 | 50.00 | 100.00 |
| ^a Amount of Type B (as-fed basis) needed to produce the component portion of the ration with desired level of monensin is as follows: | | | | |
| (Desired level of monensin in component, g/ton / g/ton of monensin in Type B) X 2000 | | | | |
| Example Top Dress: Desire 50 g/ton monensin in component, & Type B contains 500 g/ton of monensin. | | | | |
| Example Solution: (50 g/ton / 500 g/ton monensin in Type B) X 2000 = 200 lb of Type B needed per ton of Top Dress | | | | |
| ^b It is recommended that Type B feeds containing more than 1440 g/ton be further diluted before mixing into Top Dress. | | | | |
| An example of further dilution would be a ratio of 1:10 of Type B Medicated Feed:Unmedicated Feed. | | | | |
| ^c (Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: 500 g/ton / 80 g/lb = 6.25 lb Rumensin 80 per ton of Type B | | | | |

Net Weight lb on bag or bulk

**Monensin Medicated Dairy Cattle Feed
Type B Medicated Feed**

**For Use in Dairy Cattle Feeds Only
Do Not Feed Undiluted**

IMPORTANT: MUST BE THOROUGHLY MIXED INTO FEED BEFORE USE

For Increased Milk Production Efficiency (production of marketable solids-corrected milk per unit of feed intake).

Active Drug Ingredient

Monensin sodium.....23 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..... | _____ | % |
| Acid Detergent 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..... | _____ | % |
| Selenium, not less than..... | _____ | ppm |
| 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 for Total Mixed Rations

Thoroughly mix monensin Type B Medicated Feed into one ton of total mixed ration ("complete feed") to obtain the correct concentration in the Type C Medicated Feed (11 to 22 g/ton monensin in total mixed ration, 100% dry matter basis) (Table 1). [Use only the portion of the table below that is applicable to the concentration of monensin in the Type B Medicated Feed you manufacture.]

Table 1: Mixing Directions for Dairy Cow Total Mixed Rations(TMR)^a

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^b | Amount of Rumensin 80 needed per ton of Type B, lb ^c | Dry matter of TMR, % | Desired monensin concentration, g/ton in TMR ^d | | |
|---|---|----------------------|---|-------|-------|
| | | | 11 | 15 | 22 |
| 500 | 6.25 | 50 | 22.00 | 30.00 | 44.00 |
| | | 60 | 26.40 | 36.00 | 52.80 |
| 2000 | 25 | 50 | 5.50 | 7.50 | 11.00 |
| | | 60 | 6.60 | 9.00 | 13.20 |

^aAmount of Type B (as-fed basis) needed to produce the TMR with desired level of monensin is as follows:

((Desired level of monensin in TMR, g/ton) X (% dry matter of TMR)/g/ton of monensin in Type B) X 2000

Example Diet: Desire 11 g/ton monensin in TMR (dry matter basis), TMR contains 50% dry matter, & Type B contains 500 g/ton of monensin.

Example Solution: ((11 g/ton) X (0.50 dry matter of TMR) / 500 g/ton monensin in Type B) X 2000 = 22 lb of Type B needed per ton of TMR

^b It is recommended that Type B feeds containing more than 1440 g/ton be further diluted before mixing into the TMR.

An example of further dilution would be a ratio of 1:10 of Type B Medicated Feed:Unmedicated Feed.

^c (Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: 500 g/ton / 80 g/lb = 6.25 lb Rumensin 80 per ton of Type B
^d 100% dry matter basis

Mixing Directions for Component Feeding Systems (Including Top Dress)

Thoroughly mix monensin Type B Medicated Feed into one ton of component portion of the ration to obtain the correct concentration in the Type C Medicated Feed (11 to 400 g/ton monensin) (Table 2). [Use only the portion of the table below that is applicable to the concentration of monensin in the Type B Medicated Feed you manufacture.]

Table 2: Mixing Directions for Dairy Cows in Component Feeding Systems (Including Top Dress)^a

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^b | Amount of Rumensin 80 needed per ton of Type B, lb ^c | Desired Monensin Concentration, g/ton in Component Feed | | |
|---|---|---|--------|---------|
| | | 50 | 200 | 400 |
| 500 | 6.25 | lb of Type B (as-fed) per ton of component feed | | |
| | | 200.00 | 800.00 | 1600.00 |
| 2000 | 25 | 50.00 | 200.00 | 400.00 |
| 4000 | 50 | 25.00 | 100.00 | 200.00 |

^aAmount of Type B (as-fed basis) needed to produce the component portion of the ration with desired level of monensin is as follows:
(Desired level of monensin in component, g/ton / g/ton of monensin in Type B) X 2000

Example Top Dress: Desire 50 g/ton monensin in component, & Type B contains 500 g/ton of monensin.

Example Solution: (50 g/ton / 500 g/ton monensin in Type B) X 2000 = 200 lb of Type B needed per ton of Top Dress

^b It is recommended that Type B feeds containing more than 1440 g/ton be further diluted before mixing into Top Dress.

An example of further dilution would be a ratio of 1:10 of Type B Medicated Feed:Unmedicated Feed.

^c (Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: 500 g/ton / 80 g/lb = 6.25 lb Rumensin 80 per ton of Type B

Caution

Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions. Do not feed undiluted. Feeding undiluted or mixing errors resulting in high concentrations of Monensin has been fatal to cattle. 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. Must be thoroughly mixed in feeds before use.

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

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
Any town, USA 12345

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

Net Weight lb on bag or bulk

**Monensin Medicated Dairy Cattle Feed
Liquid Type B Medicated Feed**

**For Use in Dairy Cattle Feeds Only
Do Not Feed Undiluted**

IMPORTANT: MUST BE THOROUGHLY MIXED INTO FEED BEFORE USE

For Increased Milk Production Efficiency (production of marketable solids-corrected milk per unit of feed intake)

Active Drug Ingredient

Monensin sodium40 to 1440 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..... | _____ | % |
| Acid Detergent 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..... | _____ | % |
| Selenium, not less than..... | _____ | ppm |
| Vitamin A ^{2,4} , not less than..... | _____ | I.U./lb |
| pH..... | 4.3 to 7.1 | |

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 for Total Mixed Rations

Thoroughly mix monensin Type B Medicated Feed into one ton of total mixed ration (complete feed) to obtain the correct concentration in the Type C Medicated Feed (11 to 22 g/ton monensin in total mixed ration (complete feed), 100% dry matter basis) (Table 1). [Use only the portion of the table below that is applicable to the concentration of monensin in the Type B Medicated Feed you manufacture.]

Table 1: Mixing Directions for Dairy Cow Total Mixed Rations(TMR)^a

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis | Amount of Rumensin 80 needed per ton of Type B, lb ^b | Dry matter of TMR, % | Desired monensin concentration, g/ton in TMR ^c | | |
|--|---|----------------------|---|-------|-------|
| | | | 11 | 15 | 22 |
| 500 | 6.25 | 50 | lb of Type B (as-fed) needed per ton of TMR | | |
| | | 60 | 22.00 | 30.00 | 44.00 |
| 1440 | 18 | 50 | 7.64 | 10.42 | 15.28 |
| | | 60 | 9.17 | 12.50 | 18.33 |

^aAmount of Type B (as-fed basis) needed to produce the TMR with desired level of monensin is as follows:

((Desired level of monensin in TMR, g/ton) X (% dry matter of TMR)/g/ton of monensin in Type B) X 2000

Example Diet: Desire 11 g/ton monensin in TMR (dry matter basis), TMR contains 50% dry matter, & Type B contains 500 g/ton of monensin.

Example Solution: ((11 g/ton) X (0.50 dry matter of TMR) / 500 g/ton monensin in Type B) X 2000 = 22 lb of Type B needed per ton of TMR

^b(Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: 500 g/ton / 80 g/lb = 6.25 lb Rumensin 80 per ton of Type B

^c 100% dry matter basis

Mixing Directions for Component Feeding Systems (Including Top Dress)

Thoroughly mix monensin Type B Medicated Feed into one ton of component portion of the ration to obtain the correct concentration in the Type C Medicated Feed (11 to 400 g/ton monensin) (Table 2). [Use only the portion of the table below that is applicable to the concentration of monensin in the Type B Medicated Feed you manufacture.]

Table 2: Mixing Directions for Dairy Cows in Component Feeding Systems (Including Top Dress)^a

| Desired monensin concentration in Type B Feed, g/ton; as-fed basis | Amount of Rumensin 80 needed per ton of Type B, lb ^b | Desired Monensin Concentration, g/ton in Component Feed | | |
|--|---|---|--------|---------|
| | | 50 | 200 | 400 |
| 500 | 6.25 | lb of Type B (as-fed) per ton of component feed | | |
| | | 200.00 | 800.00 | 1600.00 |
| 1000 | 12.5 | 100.00 | 400.00 | 800.00 |
| 1440 | 18 | 69.44 | 277.78 | 555.56 |

^aAmount of Type B (as-fed basis) needed to produce the component portion of the ration with desired level of monensin is as follows:

((Desired level of monensin in component, g/ton) / g/ton of monensin in Type B) X 2000

Example Top Dress: Desire 50 g/ton monensin in component, & Type B contains 500 g/ton of monensin.

Example Solution: (50 g/ton / 500 g/ton monensin in Type B) X 2000 = 200 lb of Type B needed per ton of Top Dress

^b(Desired concentration of monensin in Type B feed, g/ton) / 80 g/lb. Example: 500 g/ton / 80 g/lb = 6.25 lb Rumensin 80 per ton of Type B

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 or agitation of monensin liquid Type B Medicated Feed has resulted in increased monensin concentration, which has been fatal to cattle. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions. Do not feed undiluted. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle. 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. Must be thoroughly mixed in feeds before use.

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

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
Any town, USA 12345

Expiration Date: 8 weeks after manufacture

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

Net Weight lb on bag or bulk

**Monensin Medicated Dairy Cattle Feed
Type C Medicated Feed**

For Component Feeding Systems (Including Top Dress)

For Use in Dairy Cattle Feeds Only

For Increased Milk Production Efficiency (production of marketable solids-corrected milk per unit of feed intake).

Active Drug Ingredient

Monensin sodium11 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..... | _____ | % |
| Acid Detergent 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..... | _____ | % |
| Selenium, not less than..... | _____ | ppm |
| 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 continuously to dry and lactating dairy cows in a component or top dress a Type C Medicated Feed containing 11 to 400 g/ton monensin. The Type C Medicated Feed must be fed in a minimum of 1 pound of feed per cow per day to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows (Table 1). This provides cows with similar amounts of monensin they would receive by consuming total mixed rations containing 11 to 22 g/ton monensin on a 100% dry matter basis. Use the table below to determine the amount of Type C Medicated Feed needed. Use only the portion of the table applicable to your Type C Medicated Feed.

Table 1. Feeding Directions in Which Monensin is Delivered in a Type C Medicated Feed for Component Feeding Systems (Including Top Dress).

| Amount of Type C Medicated Feed (lb/head/day) of a given concentration (g/ton) to deliver a desired amount of monensin (mg/head/day) | | | | | Equivalent Monensin Consumption in Total Dry Matter Intake (g/ton) |
|--|------|------|-----|-------------------------------|--|
| Dry Cow Example [Assuming total dry matter intake is 25 lb/head/day] | | | | Monensin Intake (mg/head/day) | |
| Monensin Concentration in Type C (g/ton, as fed) ^a | 50 | 100 | 200 | | |
| Amount of Type C to feed (lb/head/day) ^b | 5.5 | 2.8 | 1.4 | 138 | 11 |
| | 7.5 | 3.8 | 1.9 | 188 | 15 |
| | 11.0 | 5.5 | 2.8 | 275 | 22 |
| Lactating Cow Example [Assuming total dry matter intake is 50 lb/head/day] | | | | | |
| Monensin Concentration in Type C (g/ton, as fed) ^a | 50 | 100 | 400 | | |
| Amount of Type C to feed (lb/head/day) ^b | 11.0 | 5.5 | 1.4 | 275 | 11 |
| | 15.0 | 7.5 | 1.9 | 375 | 15 |
| | 22.0 | 11.0 | 2.8 | 550 | 22 |

^aThe concentration of monensin in the Type C medicated feed must be between 11 and 400 g/ton (as-fed basis)

^bAmount of Type C medicated feed (as-fed basis) needed to produce the total diet with desired level of monensin is as follows:
 (Total dry matter intake, lb/hd/day) X (desired level of monensin in the total diet ration, g/ton) / (monensin concentration in Type C feed, g/ton as-fed basis)

Example Diet: Dry matter intake is 50 lb/cow/day, desire 22 g/ton in total ration, medicated Type C contains 400 g/ton monensin.

Example Solution: (50 lb DMI) X (22 g/ton) / (400 g/ton) = 2.8 lb of Type C medicated feed needed per cow per day

Caution

Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated 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 monensin has been fatal to cattle. 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. Must be thoroughly mixed in feeds before use.

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

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
Any town, USA 12345

Expiration Date: Type C cattle feeds containing 30 grams or less monensin sodium per ton 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 lb on bag or bulk

**Monensin Medicated Dairy Cattle Feed
Type C Medicated Feed**

For Total Mixed Rations

For Use in Dairy Cattle Feeds Only

For Increased Milk Production Efficiency (production of marketable solids-corrected milk per unit of feed intake).

Active Drug Ingredient

Monensin sodium11 to 22 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..... | _____ | % |
| Acid Detergent 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..... | _____ | % |
| Selenium, not less than..... | _____ | ppm |
| 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 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.

Caution

Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated 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 monensin has been fatal to cattle. 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. Must be thoroughly mixed in feeds before use.

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

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
Any town, USA 12345

Expiration Date: 30 days after manufacture

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