

FREEDOM OF INFORMATION SUMMARY

SEP 27 2001

I. GENERAL INFORMATION:

NADA: 115-581

Sponsor: MoorMan's, Inc.
1000 North 30th Street
Post Office Box C1
Quincy, IL 62305-3115

Established Name: Monensin Sodium

Trade Name: Rumensin®

Marketing Status: OTC

Effect of Supplement: This supplement provides for the addition of the claim "for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*" to MoorMan's Type C monensin medicated free-choice protein-mineral blocks (MoorMan's Mintrate Blonde Block RU and MoorMan's Mintrate Red Block RU).

II. INDICATIONS FOR USE:

For increased rate of weight gain; and prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) on pasture which may require supplemental feed.

III. DOSAGE FORM, DOSAGE, AND ADMINISTRATION:

- A. *Dosage Form:* Rumensin® is a Type A Medicated Article available in 50-lb bags containing 80 g monensin sodium/lb. The monensin medicated blocks are Type C free-choice feeds containing 300 g monensin sodium/ton.
- B. *Route of Administration:* Orally, as a free-choice Type C medicated protein-mineral feed block.
- C. *Recommended Dosage:* Feed continuously on a free choice basis at the rate of 50 to 200 milligrams monensin per head per day.

Note: MoorMan's has authorization to reference data and information in Elanco's NADA 095-735 for monensin to support the safety and effectiveness of their products.

IV. EFFECTIVENESS:

Data supporting the effectiveness of previously approved indications are discussed in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 22, 1990, December 16, 1998, and July 31, 2000). No new data were required for the approval of this supplement.

V. SAFETY FOR THE TARGET SPECIES:

Data supporting the target animal safety of Rumensin® (monensin) Type A Medicated Article are summarized in the FOI Summaries for NADA 095-735 (supplemental approvals dated October 23, 1995, July 15, 1996, and July 31, 2000). No additional data were required for approval of this supplement.

VI. HUMAN SAFETY:

Data supporting the human food safety of Rumensin® (monensin) Type A Medicated Article are summarized in the original FOI Summary for NADA 095-735. The acceptable daily intake (ADI) for total residues of monensin is 12.5 micrograms per kilogram of body weight, while the tolerance is 0.05 part per million for negligible residues of monensin in edible tissues of cattle (21 CFR 556.420).

VII. 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 50-200 mg monensin/head/day when used in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) is safe and effective for the supplemental claim of prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions for use by the layman have been provided and the product will retain its over-the-counter marketing status.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

VIII. LABELING

The following labeling is attached:

1. MoorMan's® Mintrate® Blonde Block RU
2. MoorMan's® Mintrate® Blonde Red RU

MoorMan's[®] Mintrate[®] Blonde Block RU

Type C Medicated Feed A Free-choice Supplement for Growing Cattle and Dairy Heifers on Pasture

For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) on pasture which may require supplemental feed.

Active Drug Ingredient

Monensin (as monensin sodium) 300 grams per ton (150 milligrams per pound).

CAUTION: Feed only in accordance with instructions.

GUARANTEED ANALYSIS

Crude Protein, not less than	42.0%
(This includes not more than 12% equivalent crude protein from non-protein nitrogen.)	
Crude Fat, not less than	0.5%
Crude Fiber, not more than	7.0%
Acid Detergent Fiber (ADF), not more than	10.0%
Calcium (Ca), not less than	2.5%
Calcium (Ca), not more than	3.5%
Phosphorus (P), not less than	1.5%
Salt (NaCl), not less than	3.5%
Salt (NaCl), not more than	4.5%
Potassium (K), not less than	1.2%
Selenium (Se), not less than	4.9 ppm
Vitamin A, not less than 60,000 International Units per pound.	

INGREDIENTS

Soybean Meal, Cottonseed Meal, Dehulled Soybean Meal, Corn Gluten Feed, Cane Molasses, Calcium Carbonate, Salt, Urea, Monocalcium Phosphate, Linseed Meal, Dicalcium Phosphate, Calcium Sulfate, Hemicellulose Extract, Defluorinated Phosphate, Manganous Oxide, Zinc Oxide, Copper Sulfate, Magnesium Oxide, Ferrous Sulfate, Mineral Oil, Potassium Sulfate, Vitamin A Acetate, Potassium Iodide, Vitamin E Supplement, Sodium Selenite, Cobalt Carbonate, D-Activated Animal Sterol(Source of Vitamin D₃).

MoorMan's, Inc.,
General Office, Quincy, Illinois 62305-3115

NET WT 33¹/₃ LB (15.11 kg)

INSTRUCTIONS FOR FEEDING

MoorMan's Mintrate Blonde Block RU Medicated is for unconfined growing cattle on good quality pasture or roughage. If the pasture is in short supply or poor quality, MoorMan's Mintrate Red Block RU Medicated is recommended. Before feeding MoorMan's Mintrate Blonde Block RU Medicated, be sure cattle are accustomed to protein blocks by feeding unmedicated Mintrate Blocks for 30 to 60 days or until cattle have demonstrated proper consumption. As soon as cattle have demonstrated proper consumption, remove the non-medicated blocks and replace with the recommended amount of MoorMan's Mintrate Blonde Block RU Medicated. Feed this block free-choice. Do not allow animals access to other protein blocks, salt or mineral while being fed this product. The effectiveness of this block in cull cows and bulls has not been established.

Recommended consumption of MoorMan's Mintrate Blonde Block RU Medicated is 0.34 lb to 1.33 lb per head per day. A 10-day supply of blocks may be put out at one time. Place blocks near watering or loafing areas. Not less than one block for each 10 to 12 animals is recommended. Additional blocks should be put out when the current blocks are 75% consumed.

If consumption of MoorMan's Mintrate Blonde Block RU Medicated is higher than desired or above recommended levels - switch to MoorMan's Mintrate Red Block RU Medicated.

MoorMan's Mintrate Blonde Block RU Medicated is not a complete feed and must be fed with adequate pasture or roughage. If the pasture or roughage supplies inadequate energy for satisfactory performance, grain should be fed.

Drug Level: When cattle consume from 0.34 to 1.33 lb per head per day of this product, they will receive from 50 to 200 mg monensin per head per day.

CAUTION: Do not allow horses or other equines access to this formulation. Ingestion of monensin by equines has been fatal. Consumption of this product by sheep and goats may result in copper toxicity. Do not feed to lactating dairy cows.

PRODUCT NO. 532
Code 15

MoorMan's[®] Mintrate[®] Red Block RU

Type C Medicated Feed A Free-choice Supplement for Growing Cattle and Dairy Heifers on Pasture

For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) on pasture which may require supplemental feed.

Active Drug Ingredient

Monensin (as monensin sodium) 300 grams per ton (150 milligrams per pound).

CAUTION: Feed only in accordance with instructions.

GUARANTEED ANALYSIS

Crude Protein, not less than	38.0%
(This includes not more than 12% equivalent crude protein from non-protein nitrogen.)	
Crude Fat, not less than	1.0%
Crude Fiber, not more than	6.5%
Acid Detergent Fiber (ADF), not more than	9.0%
Calcium (Ca), not less than	2.6%
Calcium (Ca), not more than	3.6%
Phosphorus (P), not less than	1.5%
Salt (NaCl), not less than	12.0%
Salt (NaCl), not more than	14.4%
Potassium (K), not less than	1.0%
Selenium (Se), not less than	4.9 ppm
Vitamin A, not less than 60,000 International Units per pound.	

INGREDIENTS

Soybean Meal, Salt, Cottonseed Meal, Dehulled Soybean Meal, Corn Gluten Feed, Calcium Carbonate, Lignin Sulfonate, Urea, Monocalcium Phosphate, Linseed Meal, Dicalcium Phosphate, Iron Oxide, Calcium Sulfate, Cane Molasses, Hemicellulose Extract, Defluorinated Phosphate, Manganous Oxide, Zinc Oxide, Copper Sulfate, Magnesium Oxide, Ferrous Sulfate, Mineral Oil, Potassium Sulfate, Vitamin A Acetate, Potassium Iodide, Vitamin E Supplement, Sodium Selenite, Cobalt Carbonate, D-Activated Animal Sterol (Source of Vitamin D₃).

MoorMan's, Inc.,
General Office, Quincy, Illinois 62305-3115

NET WT 33¹/₃ LB (15.11 kg)

INSTRUCTIONS FOR FEEDING

MoorMan's Mintrate Red Block RU Medicated is for unconfined growing cattle on poor quality pasture or roughage or where pasture is in short supply. If the pasture or roughage is of good quality, MoorMan's Mintrate Blonde Block RU Medicated is recommended. Before feeding MoorMan's Mintrate Red Block RU Medicated, be sure cattle are accustomed to protein blocks by feeding unmedicated Mintrate Blocks for 6 to 35 days or until cattle have demonstrated proper consumption. As soon as cattle have demonstrated proper consumption, remove the non-medicated blocks and replace with the recommended amount of MoorMan's Mintrate Red Block RU Medicated. Feed this block free choice. Do not allow animals access to other protein blocks, salt or mineral while being fed this product. The effectiveness of this block in cull cows and bulls has not been established.

Recommended consumption of MoorMan's Mintrate Red Block RU Medicated is 0.34 lb to 1.33 lb per head per day. A 10-day supply of blocks may be put out at one time. Place blocks near watering or loafing areas. Not less than one block for each 10 to 12 animals is recommended. Additional blocks should be put out when the current blocks are 75% consumed.

If consumption of MoorMan's Mintrate Red Block RU Medicated is lower than desired or below recommended levels - switch to MoorMan's Mintrate Blonde Block RU Medicated.

MoorMan's Mintrate Red Block RU Medicated is not a complete feed and must be fed with adequate pasture or roughage. If the pasture or roughage supplies inadequate energy for satisfactory performance, grain should be fed.

Drug Level: When cattle consume from 0.34 to 1.33 lb per head per day of this product, they will receive from 50 to 200 mg monensin per head per day.

CAUTION: Do not allow horses or other equines access to this formulation. Ingestion of monensin by equines has been fatal. Consumption of this product by sheep and goats may result in copper toxicity. Do not feed to lactating dairy cows.

PRODUCT NO. 537
Code 16

537CK**MoorMan's® Mintrate® Red Block RU**

Type C Medicated Feed

**A Free-Choice Supplement for Growing Beef Cattle
and Dairy Heifers on Pasture**

For Increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) on pasture which may require supplemental feed.

Active Drug Ingredient

Monensin (as monensin sodium) 300 grams per ton (150 milligrams per pound.

CAUTION: Feed only in accordance with instructions.**GUARANTEED ANALYSIS**

Crude Protein, not less than	38.0%
(This includes not more than 12.0% equivalent crude protein from non-protein nitrogen.)	
Crude Fat, not less than	1.0%
Crude Fiber, not more than	6.5%
Acid Detergent Fiber (ADF), not more than	9.0%
Calcium (Ca), not less than	2.6%
Calcium (Ca), not more than	3.6%
Phosphorus (P), not less than	1.5%
Salt (NaCl), not less than	12.0%
Salt (NaCl), not more than	14.4%
Potassium (K), not less than	1.0%
Selenium (Se), not less than	4.9 ppm
Vitamin A, not less than 60,000 International Units per pound.	

INGREDIENTS

Soybean Meal, Salt, Cottonseed Meal, Dehulled Soybean Meal, Corn Gluten Feed, Calcium Carbonate, Lignin Sulfonate, Urea, Monocalcium Phosphate, Linseed Meal, Dicalcium Phosphate, Iron Oxide, Calcium Sulfate, Cane Molasses, Hemicellulose Extract, Defluorinated Phosphate, Manganous Oxide, Zinc Oxide, Copper Sulfate, Magnesium Oxide, Ferrous Sulfate, Mineral Oil, Potassium Sulfate, Vitamin A Acetate, Potassium Iodide, Vitamin E Supplement, Sodium Selenite, Cobalt Carbonate, D-Activated Animal Sterol (Source of Vitamin D3).

MoorMan's, Inc., General Office, Quincy, Illinois 62305-3115

NET WT 33¹/₃ LB (15.11 kg)**INSTRUCTIONS FOR FEEDING (For cattle only)**

MoorMan's Mintrate Red Block RU Medicated is for unconfined growing cattle on poor quality pasture or roughage or where pasture is in short supply. If the pasture or roughage is of good quality, MoorMan's Mintrate Blonde Block RU Medicated is recommended. Before feeding MoorMan's Mintrate Red Block RU Medicated, be sure cattle are accustomed to protein blocks by feeding unmedicated Mintrate Blocks for 6 to 35 days or until cattle have demonstrated proper consumption. As soon as cattle have demonstrated proper consumption, remove the non-medicated blocks and replace with the recommended amount of MoorMan's Mintrate Red Block RU Medicated. Feed this block free-choice. Do not allow animals access to other protein blocks, salt or mineral while being fed this product. The effectiveness of this block in cull cows and bulls has not been established.

Recommended consumption of MoorMan's Mintrate Red Block RU Medicated is 0.34 lb to 1.33 lb per head per day. A 10-day supply of blocks may be put out at one time. Place blocks near watering or loafing areas. Not less than one block for each 10 to 12 animals is recommended. Additional blocks should be put out when the current blocks are 75% consumed.

If consumption of MoorMan's Mintrate Red Block RU Medicated is lower than desired or below recommended levels - switch to MoorMan's Mintrate Blonde Block RU Medicated.

MoorMan's Mintrate Red Block RU Medicated is not a complete feed and must be fed with adequate pasture or roughage. If the pasture or roughage supplies inadequate energy for satisfactory performance, grain should be fed.

Drug Level: When cattle consume from 0.34 to 1.33 lb per head per day of this product, they will receive from 50 to 200 mg monensin per head per day.

CAUTION: Do not allow horses or other equines access to this formulation. Ingestion of monensin by equines has been fatal. Consumption of this product by sheep and goats may result in copper toxicity. Do not feed to lactating dairy cows.

PRODUCT NO. 537

C.No. 537CKC

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