

NADA Number: 095-735

Trade Name	Rumensin® 80 Rumensin® Rumensin® 90
Sponsor	Elanco Animal Health, A Division of Eli Lilly & Co.
Ingredients	MONENSIN
Species	CATTLE (Cattle, beef, cows) CATTLE (Cattle, dairy) CATTLE (Cattle, calves, excluding veal calves) CATTLE (Cattle, growing on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers)) CATTLE (Cattle, beef, feedlot) GOATS (Goat, confinement)
Routes of Administration	Per Os
Dosage Form	Medicated feed
Dispensing Status	OTC
Patent Number (Expiration Date)	3839557 (No Expiration Date) 3995027 (No Expiration Date) 4061755 (No Expiration Date) 4075323 (No Expiration Date) 4083962 (No Expiration Date) 4218438 (No Expiration Date) 4333919 (No Expiration Date) 4366168 (No Expiration Date) 4405609 (No Expiration Date) 4468380 (No Expiration Date)
Exclusivity	This OTC supplemental approval provides for the expanded use of the drug to prevent coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> in feedlot cattle. The product is approved in premix form in a concentration of 60 g/lb. Granted for weight gain in pasture cattle (removing the weight previous limitation). Granted for the use of monensin used at the rate of 11 to 22 grams per ton of total mixed ration (dry matter) in dairy cows for increased milk production efficiency (defined as production of marketable solids per unit of feed intake). Granted for prevention and control of coccidiosis in pasture cattle, mature reproducing beef cows, and non-veal calves.
Dosage Amount, Indications & Limitations	558.355 Monensin. Specifications: Monensin as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Approvals for Type A medicated articles containing 20, 30, 45, 60, 80 and 90.7 grams per pound, as monensin sodium. Growing cattle on pasture or in dry lot Amount: Monensin, 15 to 400 grams per ton of feed. Indications: 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 prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> . Limitations: For increased rate of weight gain, feed at a rate of not less than 50 nor more than 200 milligrams monensin per head per day in not less than 1 pound of Type C medicated feed or; after the 5th day, feed at a rate of 400 milligrams 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 15 and 400 g/ton. During the first 5 days, cattle should receive no more than 100 milligrams per day contained in not less than 1 pound of feed. Do not self feed. For prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> feed at a rate to provide 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to a maximum of 200 milligrams per head per day. The monensin concentration in the Type C medicated feed must be between 15 and 400 g/ton. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed. Mature reproducing beef cows Amount: Monensin, 25 to 400 grams per ton of feed. Indications: For improved feed efficiency; for prevention and control of coccidiosis due to <i>E. bovis</i> and <i>E. zuernii</i> . Limitations: Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending

upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

Feedlot cattle

Amount: Monensin, 5 to 40 grams per ton.

Indications: Improved feed efficiency.

Limitations: Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day).

Amount: Monensin, 10 to 40 grams per ton of feed.

Indications: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

Limitations: For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

Growing cattle on pasture or in dry lot

Amount: Monensin, 1620 grams as monensin sodium (810 milligrams per pound).

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

Specifications: Use as free-choice Type C medicated feed formulated as mineral granules (listed as percents) as follows: Monocalcium phosphate (29.49) Sodium chloride (salt) (24.25) Dried cane molasses (20.0) Ground limestone (33 percent Calcium) or calcium carbonate (38 percent Calcium) (13.75) Cane molasses (3.0) Processed grain by-products (5.0) Vitamin/trace mineral premix (2.5) Monensin Type A article, (1.01) Anti-dusting oil (1.0) NOTE: Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements.

Limitations: Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows and bulls has not been established. Consumption by unapproved species may result in toxic reactions. A feed manufacturing facility must possess a medicated feed mill license issued under Sec. 515.20 of this chapter in order to manufacture this free-choice Type C feed. Do not feed to lactating dairy cattle.

Cattle, calves excluding veal

Amount: Monensin, 10 to 200 grams per ton of feed.

Indications: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

Limitations: For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

Labeling: The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

Cattle, dairy cows

Amount: Monensin, 11 to 22 grams per ton.

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

Limitations: Feed continuously to dry and lactating cows in a total mixed ration ("complete feed").

Amount: Monensin, 11 to 400 grams per ton.

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

Limitations: Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). 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.

Goats, confined

Amount: Monensin, 20 grams per ton of feed.

Indications: For the prevention of coccidiosis caused by *Eimeria crandallis*, *E. christenseni*, and *E. ninakohlyakimovae*.

Limitations: Feed continuously. Feed only to goats being fed in confinement. Do not feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions. Inadequate mixing of liquid Type B feeds has resulted in increased monensin concentration which could be fatal to goats. Do not allow horses or other equine species access to formulations containing monensin. Ingestion of monensin by these species has been fatal. Monensin medicated goat feed is safe for use in goats only. Consumption by unapproved species may result in toxic reactions. Must be thoroughly mixed in feeds before use, high concentrations of monensin resulting from mixing errors could be fatal to goats; Do not feed undiluted; Do not exceed the levels of monensin recommended in the feeding directions as reduced average daily gains may result.

Labeling: The labeling of Type A articles and Type B feeds (liquid and dry) containing monensin for use in goats shall bear the following caution statements:

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