

Rumensin® for Dairy Cows

(monensin sodium)

FAQ

Frequently Asked Questions

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Rumensin® is a trademark for Elanco's brand of monensin sodium

POSILAC® is Monsanto's trade name for supplemental bovine somatotropin



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1 Rumensin Description

A. What is Rumensin?

Rumensin is the only U.S. Food and Drug Administration (FDA) approved feed ingredient for lactating and dry cows that increases milk-production efficiency (production of marketable solids-corrected milk per unit of feed intake) by economically delivering more milk per pound of feed while maintaining the natural wholesomeness of milk.

Rumensin is a registered trademark for Elanco's brand of monensin sodium. Rumensin is a product of fermentation and a member of a class of compounds called ionophores. The only ionophore approved for use in lactating and dry cows in the United States, Rumensin changes the microbial populations in the cow's rumen. This promotes more efficient energy production in the rumen. Rumensin has been fed to beef and dairy cattle for more than 20 years.

B. What is the claim?

The new claim, for use in dairy cows, as approved by the FDA is "for increased milk-production efficiency (production of marketable solids-corrected milk per unit of feed intake). Rumensin is approved at a dietary concentration of 11 to 22 grams per ton of a total mixed ration (complete feed) on a 100 percent dry matter basis."

For years, Rumensin has been used by dairy producers in calves and heifers for prevention and control of coccidiosis. It is also approved for improvement in average daily gain in replacement heifers on pasture.

C. Is Rumensin a hormone or an antibiotic?

Rumensin is not a hormone. It belongs to a class of antibiotics called ionophores, which are used exclusively in animals. They are not used for the treatment or prevention of disease (bacterial or otherwise) in humans. Rumensin is not related by structure or mode of action to any antibiotic used in human medicine. There are no known monensin-resistance genes, which means that resistance is not transferable between bacteria.

2 Performance

A. How effective is Rumensin?

Rumensin improves milk-production efficiency by 1.8 percent to 3.9 percent when fed throughout lactation and the dry period.

B. Does Rumensin deliver more energy from forages as well as concentrates?

Yes. Rumensin works in all types of rations. In addition, Rumensin may allow some dairies to feed a "healthier" ration—one with more effective fiber that stimulates rumination and buffering—while increasing the net energy of the ration.

C. Will dairy cows on pasture benefit from Rumensin?

In the trials conducted by Elanco for FDA approval, cattle were fed a total mixed ration. The feeding directions indicate that Rumensin is to be fed continuously to dry and lactating dairy cows in a total mixed ration (complete feed) containing 11 to 22 g/ton monensin on a 100 percent dry matter basis. Rumensin is FDA-approved for use in dairy replacement heifers on pasture.

D. Will all dairy breeds benefit from being fed Rumensin?

The trials conducted by Elanco for FDA approval were conducted with Holstein dairy cattle. Rumensin has been used successfully in more than 20 countries, where other breeds of dairy cattle are more prominent. Elanco recommends working with your nutritional advisors to determine the optimal Rumensin feeding program for your herd.

E. What is milk-production efficiency?

The claim for increased milk-production efficiency was calculated using marketable solids-corrected milk divided by net energy intake, adjusted for body weight change. In practical terms, this means more milk per pound of feed. Cows consuming Rumensin get more energy from every pound of feed and thus convert feed into milk more efficiently.

F. Does feeding Rumensin affect dry matter intake (DMI)?

Dry matter intake is not affected during early lactation while cows fed Rumensin are in negative energy balance. Once energy balance is achieved, Rumensin delivers more energy from every pound of feed so cows reduce their feed intake while maintaining production levels.

G. Does Rumensin change feed intake in transition cows?

Before calving, Rumensin-fed cows may adjust their intake based on their energy demand and energy availability from their ration. In early lactation when cows are in negative energy balance, dry matter intake is not affected by feeding Rumensin.

H. How much does it cost to feed Rumensin?

Rumensin costs pennies per cow per day. The exact cost will depend on the feeding level and intake of each herd.

I. What is a typical return on investment when feeding Rumensin to dairy cows?

On average, Elanco trials demonstrated a 5:1 return when used at the recommended levels to improve milk-production efficiency.

J. Does Rumensin affect mastitis or somatic cell counts in milk?

No. Feeding Rumensin does not affect susceptibility to mastitis or somatic cell counts in milk.

K. Will adding Rumensin to the ration affect body weight or body condition score?

Body weight and body condition score were observed regularly for each animal included in the Elanco-conducted trials for FDA approval. Body weight and body condition score at the end of lactation were similar to control cows.

L. Does feeding Rumensin increase abortion rates or affect calving ease?

No.

3 Milk Composition and Quality

A. What effect does Rumensin have on milkfat?

In Elanco trials conducted for FDA approval, milkfat percent was decreased; however, daily yield was not significantly affected. Many factors such as genetics, stage of lactation, ration characteristics and environment affect the milkfat percent in your herd. Work closely with your dairy advisors to use Rumensin successfully and manage factors that impact milkfat percent and yield.

B. How does feeding Rumensin affect milk protein?

In Elanco trials conducted for FDA approval, milk protein percent was reduced at the 22 g/ton dose. However, protein yield was numerically increased at all three doses, indicating that the reduction in percent was due to dilution.

C. What effect does Rumensin have on other milk components?

Milk from dairy cows fed Rumensin throughout lactation had normal protein fractions (caseins and whey fractions). Fat and total solids in milk were decreased with an increasing dose of Rumensin. The mineral content was slightly increased, especially calcium, magnesium and zinc. Milkfat produced by cows fed Rumensin had increased vaccenic and conjugated linoleic acid contents.

D. Does feeding Rumensin have an effect on milk's manufacturing qualities?

Studies show that Rumensin does not affect the development of acidity by cheese or yogurt starter cultures, or the manufacturing properties of milk for making cheese.

E. Does Rumensin change the sensory quality of milk and other dairy products?

No. Feeding Rumensin does not affect the sensory qualities of milk or cheeses manufactured from the milk.

4 “You May Notice” Section of Label

▶ 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.

A. Why does Rumensin reduce feed intake in dairy cows?

Rumensin provides more energy from the ration. Dry matter intake is not affected during early lactation, while cows fed Rumensin are in negative energy balance. Once energy balance is achieved, cows reduce their feed intake while maintaining production levels.

B. How much change in dry matter intake can be expected when feeding Rumensin?

Table 1 shows the dry matter intake results from Elanco's trials conducted for FDA approval.

Table 1. Dry matter intake (lbs/hd/day)

	Rumensin feeding level			
	0 (control)	11 g/ton*	15 g/ton	22 g/ton
Lactating Cows				
Average dry matter intake (lbs)	43.9	43.3	42.8	42.3
% change from control		-1.4	-2.5	-3.6
Dry Cows				
Average dry matter intake (lbs)	28.2	27.5	27.5	26.5
% change from control		-2.5	-2.5	-6.0

*Values interpreted from Elanco trial data

▶ YOU MAY NOTICE:

Reduced milkfat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed.

C. Does Rumensin reduce milkfat yield?

In Elanco trials conducted for FDA approval, milkfat percent was decreased. However, daily fat yield was not significantly affected. Many factors such as genetics, stage of lactation, ration characteristics and environment affect the milkfat percent in your herd. Work closely with your dairy advisors to use Rumensin successfully and manage factors that impact milkfat percent and yield.

D. What are the best methods for maintaining milkfat levels when feeding Rumensin?

Many factors such as genetics, stage of lactation, ration characteristics and environment affect the milkfat percent and yield in your herd. The major ration characteristics affecting milkfat are levels of effective fiber and other carbohydrates. It is important to maintain a diet with proper effective fiber levels when using Rumensin. Work closely with your dairy advisors to use Rumensin successfully.

E. When I start feeding Rumensin, how long will it take to see a reduction in milkfat percent and how long might it last?

If a reduction in milkfat percentage is going to occur, it will be evident within 2 to 3 weeks, and it is likely to persist throughout lactation if the ration remains the same. All of the factors that influence Rumensin's affect on milkfat percentage are not known at this time. However, normal ration changes used to avoid milkfat reduction are likely to be helpful when milkfat percent is reduced with Rumensin. Work closely with your nutritional advisors to use Rumensin successfully.

▶ YOU MAY NOTICE:

Increased incidence and treatment of cystic ovaries and metritis in dairy cows fed monensin.

F. Did the incidence of cystic ovaries and metritis result in a reduction in reproductive performance?

In Elanco trials conducted for FDA approval, pregnancy rate did not differ among treatments during either study lactation. Even though fertility appeared to be reduced in Rumensin-treated cows as reflected in results for services per animal and conception rate, overall pregnancy rate did not differ, indicating that any reduction in fertility is likely a manageable effect of Rumensin use in dairy cows.

G. What was the incidence of cystic ovaries and metritis in the trials?

The results from Elanco trials conducted for FDA approval are shown in Tables 2, 3 and 4. The increased incidence of cystic ovaries was observed only in primiparous cows.

Table 2. Animal Rate for Cystic Ovarian Disease in Lactation 1.

Variable	Rumensin (g/ton)				Industry Goal ¹
	0	7	15	22	
Number heifers observed	6	8	13	15	
Number heifers at risk	84	88	84	87	
Animal rate ^b	6.1	7.3	13.3 ^a	14.7 ^a	<10
Number cows observed	22	21	23	24	
Number cows at risk	152	150	150	147	
Animal rate ^a	12.9	11.6	13.0	13.6	<10

^a P ≤ .10 compared to control

^b P ≤ .10 for linear dose trend

¹Number of cows observed per number of cows at risk

Table 3. Animal Rate for Cystic Ovarian Disease in Lactation 2*.

Variable	Rumensin (g/ton)				Industry Goal ¹
	0	7	15	22	
Number observed	12	5	10	9	
Number at risk	63	64	60	62	
Animal rate	19.0	7.8	16.7	14.5	<10

*Calving 2 to ~200 DIM (3 sites)

Table 4. Animal Rate for Metritis in Lactations 1 and 2.

Variable	Rumensin (g/ton)				Industry Goal ¹
	0	7	15	22	
Lactation 1					
Number observed	38	50	60	57	
Number at risk	236	238	234	234	
Animal rate ^b	14.9	20.8	23.7 ^a	22.6	<10
Lactation 2b**					
Number observed	8	9	12	9	
Number at risk	63	64	60	62	
Animal rate	12.7	14.1	20.0	14.5	<10

**Lactation 2b—Calving 2 to ~200 DIM (3 sites)

Animal rate values for Lactation 1 are adjusted for factors in the statistical model

^a P ≤ .10 compared to control

^b P ≤ .10 for linear dose trend

H. What were the actual trial results for the reproductive traits listed in this notification?

YOU MAY NOTICE:

Reduced conception rates, increased services per animal and extended days open, and corresponding calving intervals in dairy cows fed monensin.

The results from the Elanco-conducted trials for FDA approval are shown in Tables 5 and 6.

Table 5. Estrous Activity for Cows in Lactation 1.

Variable	Rumensin (g/ton)				Industry Goal ¹
	0	7	15	22	
Number of cows (50 DIM*)	218	211	219	221	
Days to first-observed standing estrus	74.5	73.8	68.6	73.0	
Days to first service	84.1	84.7	86.9	83.6	<80

*50-day voluntary wait period

Table 6. Breeding Efficiency in Lactation 1.

Variable	Rumensin (g/ton)				Industry Goal ¹
	0	7	15	22	
Cows inseminated	213	209	213	216	
Services per conception (all cows)	2.43	2.52	2.71	2.77	
Services per conception (pregnant cows)	1.79	1.90	1.75	1.97	≤2
First-service conception rate (%)	49.1	41.6	44.5	36.4 ^a	50
Overall conception rate (%)	42.8	41.4	40.0	37.6	50
Days open	99.8	104.6	100.4	107.7 ^a	85–115
Percent calving*	64.6	63.1	62.0	68.6	65–70
21-day pregnancy rate	21.5	20.3	18.7	19.2	18–22

^a P ≤ .05 compared to control

*Percent cows eligible for breeding that calved following a normal, full gestation.

YOU MAY NOTICE:

Have a comprehensive and ongoing nutritional, reproductive and herd-health program in place when feeding monensin to dairy cows.

I. Is this recommendation unique to feeding Rumensin?

No. Elanco recommends that all producers, regardless of their use of Rumensin, work with their nutritional advisors, reproductive specialists and other herd consultants to develop and maintain ongoing nutritional, reproductive and herd-health programs.

5 Recommended-use Program

A. What is Elanco's recommended-use program for feeding Rumensin to dairy cows?

Elanco recommends that you begin feeding Rumensin to all cows at 11 g/ton, and then work with your nutritional advisors to determine the feeding level that is best for your herd.

B. Why doesn't Elanco recommend starting to feed Rumensin at the 15 g/ton or 22 g/ton levels?

Starting to feed Rumensin to all cows at 11 g/ton allows producers to evaluate its impact on various aspects of their operation. This enables producers, with the help of their nutritional advisors, to learn how to manage Rumensin to its greatest potential. This recommendation also increases the likelihood of a favorable first experience with Rumensin, since the effects described in the "You May Notice" section of the Rumensin label were most noticeable at higher doses.

C. In what type of rations does Rumensin work best?

Rumensin enables cows to get more energy from any ration. Elanco recommends that producers work with their nutritional advisors to determine the feeding program and Rumensin dose that's best for their herds.

D. Does anything in the ration need to be changed when Rumensin is added?

All Elanco trials for FDA approval used locally available feedstuffs. The rations were formulated to provide levels of energy, protein and other nutrients recommended by the National Research Council.

E. Why does the Rumensin label show approved feeding levels from 11 to 22 g/ton when the trials were conducted using from 7 to 22 g/ton?

In the Elanco trials used for approval, there was a linear increase in milk-production efficiency with increasing doses of monensin. FDA used a statistical method to determine that 11 g/ton of Rumensin was the lowest feeding level that yielded a significant improvement in milk-production efficiency.

F. What is the effect of starting and stopping the use of Rumensin?

The benefits of Rumensin are derived from continuous use throughout lactation and the dry period. The full benefit of increased milk-production efficiency will be lost if Rumensin is removed from the diet. Elanco has not conducted studies to evaluate the intermittent use of Rumensin in dairy cows.

G. Does Rumensin do the same thing as POSILAC?

No. Rumensin and POSILAC work differently and independently. Rumensin improves efficiency of rumen fermentation to get more energy out of every pound of feed thus making more nutrients available. This increased efficiency results in more milk produced for every pound of feed consumed. POSILAC or bST coordinates the metabolism of nutrients such that more nutrients are available for increased milk production after the cow has met her nutrient requirement for maintenance. Milk production increases an average of 8 to 12 pounds per day throughout lactation with the use of POSILAC.

H. What is the recommended program for using both Rumensin and POSILAC in a herd?

Elanco recommends that producers start feeding Rumensin to all cows at 11 g/ton, and work with their nutritional advisors or with Monsanto Dairy Business personnel to determine POSILAC administration according to the POSILAC label.

I. Will producers need to purchase any special equipment to incorporate Rumensin into their management programs?

No. Rumensin may be mixed into the ration using typical feed-mixing equipment. Producers should work with their nutritional advisors to determine the best methods and practices for mixing rations properly.

6 Safety

A. Is Rumensin safe?

Yes, when used according to label instructions.

B. What should employees do to safely handle Rumensin?

There is no safety hazard when Rumensin is handled properly. When mixing and handling Rumensin, use protective clothing, impermeable gloves and a dust mask. After handling, wash hands thoroughly with soap and water. If accidental eye contact occurs, immediately rinse with water. The Material Safety Data Sheet (MSDS) gives specific guidelines for safe handling procedures, and can be obtained from www.elanco.com.

C. What emergency steps should be taken if Rumensin is ingested by humans?

If you have such an exposure to Rumensin, Elanco urges you to immediately contact the Rocky Mountain Poison and Drug Center at (800) 722-0987 or the Elanco Hotline at (800) 428-4441.

D. Is there a withholding period for milk or meat from Rumensin-fed cows?

No. There is no withholding period for meat or milk from cows fed Rumensin. Rumensin meets stringent standards for food safety set by the FDA, which has determined that milk and meat from Rumensin-fed cows are safe for human consumption.

E. Can residues be found in milk from cows fed Rumensin?

Feeding Rumensin does not result in residues in meat or milk above levels considered to be negligible by FDA. It does not cause positive reaction in routine screens (Delvo P and Charm) for antibiotics in milk.

F. Is Rumensin harmful to other species?

Do not allow horses or other equines access to feeds containing Rumensin. Ingestion of monensin by horses has been fatal. Monensin-medicated cattle and goat feeds fed at approved feeding levels are safe for use in cattle and goats only.

G. What happens if I feed too much Rumensin?

If you suspect you might have fed too much Rumensin or that cattle may not be performing as expected, Elanco urges you to call its 24-hour, toll-free hotline: (800) 428-4441. High levels (5X–10X the recommended dose) of Rumensin will cause significant reduction in intake. If high levels of Rumensin are suspected, then remove suspected feed from the cows, collect a 1-pound sample of both the final feed and the Rumensin carrier, and freeze for possible assay. Instructions regarding assay submissions will be discussed when you call (800) 428-4441. Provide the cows with fresh feed containing Rumensin at the recommended dose.

H. Does Rumensin contribute to antimicrobial resistance in humans?

There is no evidence that the use of Rumensin in cattle compromises the effectiveness of antibiotics in human medicine.

- Rumensin is not approved for use in humans
- Rumensin is not related structurally to any antibiotic in human medicine
- Rumensin is not related by mode of action to any antibiotic used in human medicine

Rumensin's unique mode of action is primarily physiochemical (e.g., disruption of the ion-water balance within cells) and is not shared with any antibiotic used in human medicine. Resistance development to ionophores is unique and different from other antibiotics. Ionophores are not considered of importance to human medicine according to a guidance document issued by the FDA's Center for Veterinary Medicine.

I. Will the long-term use of Rumensin result in antibiotic resistance in cattle?

No. Rumensin's mode of action makes it extremely unlikely to contribute to the development or spread of antibiotic resistance in cattle. Rumensin works by changing populations of rumen and intestinal microorganisms, which is similar to what occurs when commonly used feed ingredients are adjusted in cattle rations. Furthermore, Rumensin continues to be effective in beef cattle after nearly 30 years of continuous use.

J. Does feeding Rumensin have an impact on the environment?

The FDA has determined that feeding Rumensin to dairy cows will not have a significant impact on the environment. In general, products that improve efficiency of milk production reduce the environmental resources needed to produce a gallon of milk.

K. Does Rumensin affect other animal or plant species in the environment?

No. Monensin, the active ingredient in Rumensin, was tested for safety in bobwhite quail, mallard ducks, bluegills, rainbow trout, two species of earthworms, 16 species of crops, green algae and soil microorganisms. Based on the results of these evaluations, and on the residues of monensin that could enter the environment through the use of manure as fertilizer, no effects are expected in the environment. Like all animal-health products, unused Rumensin should be disposed of according to the Material Safety Data Sheet.

7 Consumer Benefits

A. How does feeding Rumensin to dairy cows benefit consumers?

Rumensin is an efficiency-generating product that dairies can use to improve profitability while producing abundant supplies of wholesome milk. This, in turn, helps the food system assure a readily available, affordable supply of dairy products for consumers.

B. Will dairy products from milk produced by Rumensin-fed cows be labeled?

The FDA does not require special labeling for dairy products made from milk produced by cows fed Rumensin.



¹Radostits, OM, KE Leslie and J Fetrow. Maintaining Reproductive Efficiency in Dairy Cattle. *IN: Herd Health: Food Animal Production Medicine*, 2nd edition. W.B. Saunders Co., Philadelphia. 1994.