THE RUMENSIN® ADVANTAGE

STANDING OUT IN THE CROWD, COMMITTED TO QUALITY

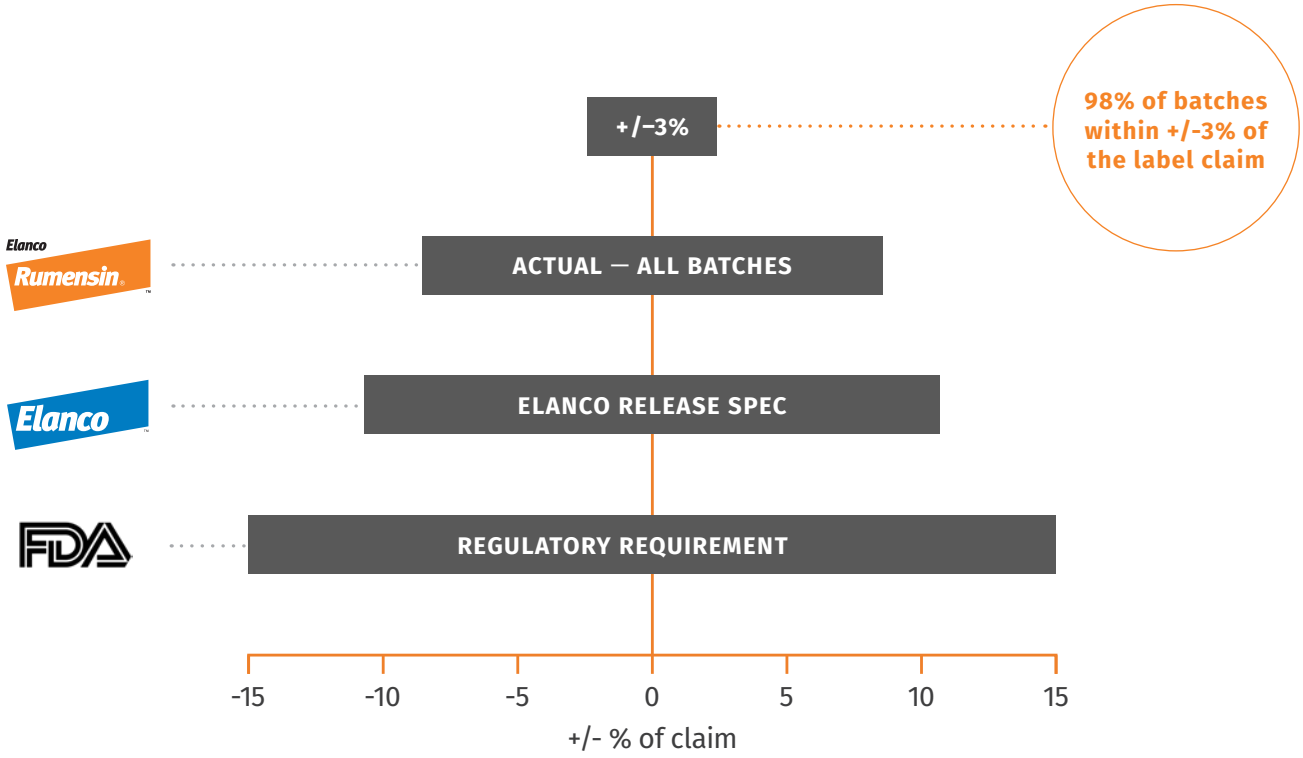
For more than 40 years, producers have trusted Rumensin to deliver consistent, dependable results that add more profit potential to the bottom line. Attention to detail sets Rumensin apart.

For Quality, Choose Rumensin

CONSISTENT POTENCY, BATCH AFTER BATCH

Rumensin manufacturing processes are highly controlled and repeatable. The target potency for Rumensin is 90.7 g/lb of monensin. **Ninety-eight percent of Rumensin batches are within +/-3% of the designated target, far surpassing the broader +/-15% range allowed by the FDA** (Figure 1).[1]

FIGURE 1.
RUMENSIN POTENCY



GENERIC DRUGS NOT APPROVED USING THE SAME EXTENSIVE DATA AND STUDIES AS PIONEER DRUGS

In 2019, the FDA approved Monovet® as a generic source of the active ingredient monensin. **Approval of Monovet did not require the same extensive studies and data that were required for Rumensin.**

Case in point: Monovet's bioequivalence to Rumensin was approved on the basis of one small-pen feedlot study and an *in vitro* dissolution study.[2]

True Differences Exist

Elanco's rigorous lab testing shows that Rumensin and Monovet differ in key ways, including:

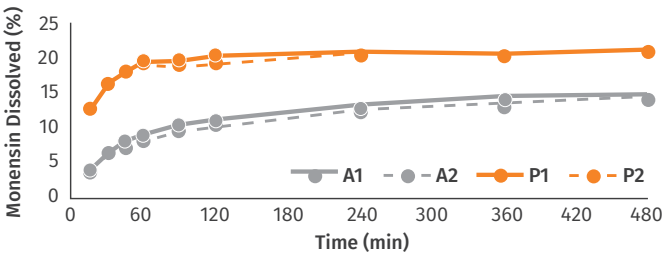
- Dissolution profile
- Product particle size characteristics

MORE RUMENSIN IS DISSOLVED

Dissolution studies are used to determine the extent to which an active ingredient dissolves in the rumen. Rumensin had higher dissolution (i.e., more of the active ingredient was dissolved) than Monovet in both high-forage-diet (Figure 2) and high-concentrate-diet (Figure 3) simulated rumen fluid evaluations.[3]

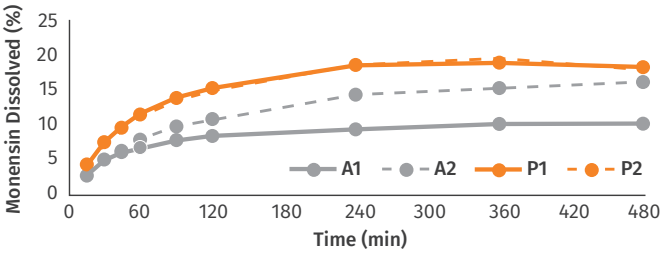
- **The test statistics in this dissolution study indicate that Rumensin and Monovet are different**
- **Data suggest that the active ingredient would be released more slowly and/or to a lesser extent from Monovet than from Rumensin under the test conditions**

FIGURE 2.
MORE RUMENSIN DISSOLVED IN SIMULATED HIGH-FORAGE-DIET RUMEN FLUID[3]



A1 = Monovet 90 lot 19051514010, A2 = Monovet 90 lot 19061514034, P1 = Rumensin 90 lot D148565, P2 = Rumensin 90 lot D148566

FIGURE 3.
MORE RUMENSIN DISSOLVED IN SIMULATED HIGH-CONCENTRATE-DIET RUMEN FLUID[3]



A1 = Monovet 90 lot 19051514010, A2 = Monovet 90 lot 19061514034, P1 = Rumensin 90 lot D148565, P2 = Rumensin 90 lot D148566

WHY DID ELANCO AND HUVEPHARMA FIND DIFFERENT DISSOLUTION RESULTS?

The studies were conducted using different laboratory conditions, such as the dissolving fluid used and the stir rate. The Elanco study used the most current United States Pharmacopeia (USP) guidelines for conducting cattle-product dissolution studies, which specify that the dissolving fluids should be simulated high-forage or high-grain rumen fluids.[4]

In the Huvepharma study, the within-lot variability exceeded the limits permitted for standard FDA interpretation procedures. In addition, an alternative statistical procedure was used that allowed for similarity to be established within a wide range of solubility.

In the Elanco study, within-lot variation was low enough to use the standard FDA statistical procedures to evaluate the dissolution profiles, and these statistical analyses showed that the two products are not similar.

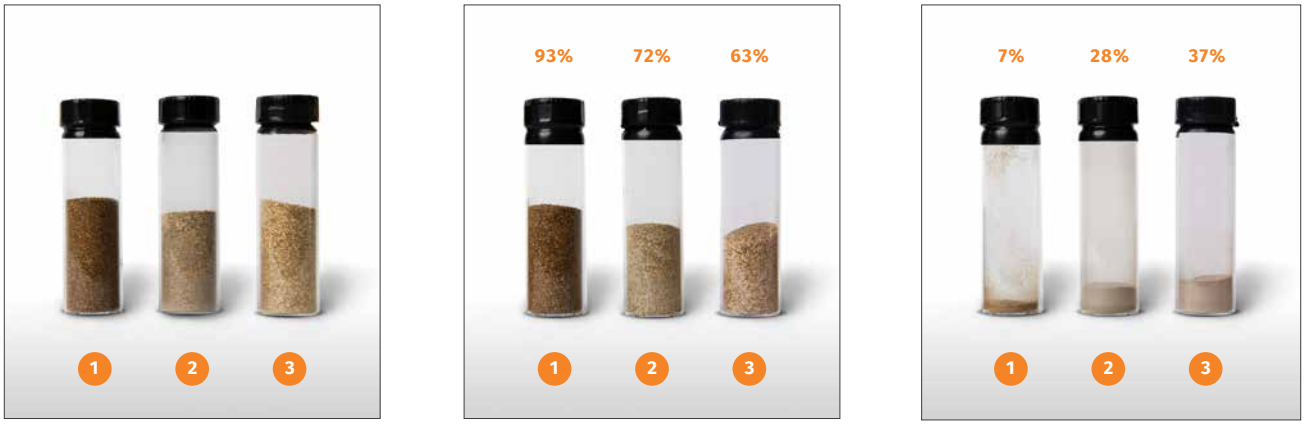
Elanco Rumensin™

Particle Size Comparison

OUT OF THE BAG

180 MICRONS TO 850 MICRONS
(appropriate size for mixing)

<180 MICRONS
(dust)



1 **RUMENSIN** 2 **MONOVET:** BATCH 1 3 **MONOVET:** BATCH 2

MORE PARTICLES SUITABLE FOR MIXING

When two randomly selected lots of Monovet were evaluated, they were found to be significantly dustier and had more particle size variability than Rumensin.[5-7]

- Ninety-three percent of Rumensin particles are within the target range for adequate mixing, compared to only 63% to 72% for Monovet (Table 1)
- Monovet has four to five times more dust particles (less than 180 microns in size) than Rumensin

TABLE 1.
MORE RUMENSIN PARTICLES SUITABLE FOR ADEQUATE MIXING[8]

Sieve Analysis	Percentage of Product Retained		
	Rumensin[5]	Monovet Batch[6]	Monovet Batch[7]
>850 microns	0%	0%	0%
180 microns to 850 microns*	**93%**	**72%**	**63%**
125 microns to 179 microns	4%	13%	19%
<125 microns	3%	15%	18%
Total dust	7%	28%	37%

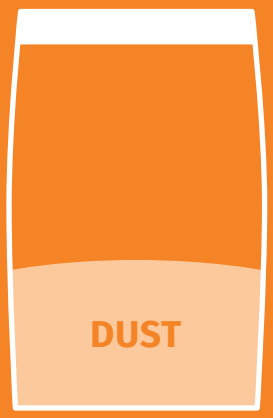
*Appropriate size for feed mixing.

The differences in dust quantities between Monovet lots demonstrate variability in its manufacturing process.

MONOVET CONTAINS 28% TO 37% DUST,[6-7] THEREFORE

A 55 lb bag of Monovet could contain more than

20 LBS OF DUST



On a pallet, more than

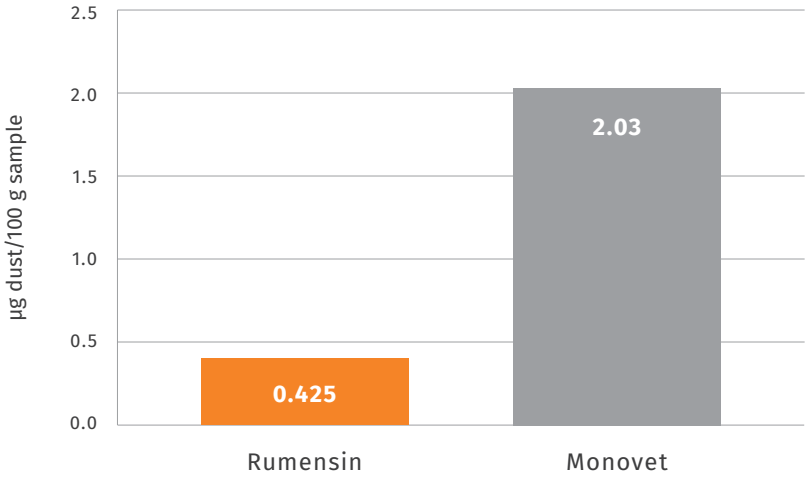
800 LBS

(the equivalent of 14 of the 40 bags) could be dust

FINE AIRBORNE DUST PARTICLE TEST

Monovet samples have nearly five times more fine airborne dust particles than Rumensin (Figure 4).[9]

FIGURE 4.



- Fine dust amounts can be measured by a Huebach analysis
- Dust particles are collected by a stream of air moving across a rolling chamber filled with the sample

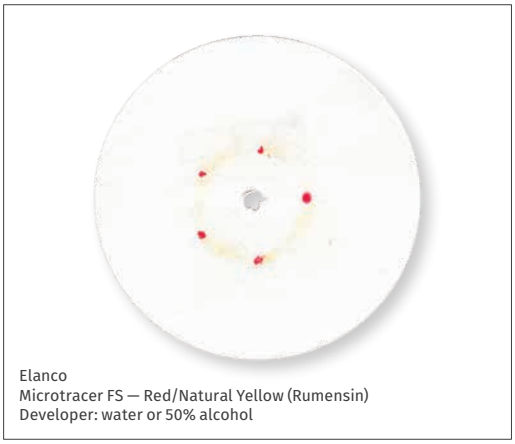
Only Rumensin Contains Microtracers®

WHAT ARE MICROTRACERS?

- Very small metallic particles coated with feed-grade dye and blended into Rumensin at low levels
- No impact on the feed, animals or environment
- Detected at the feed mill with an easy, quick test

WHY ARE MICROTRACERS USED?

- Accurately determine if Rumensin is present in feed
- Provide an estimate of the level of Rumensin
- Validate Rumensin is not present in feed
- Confirm proper feed mixing procedures



Example of a Rumensin Microtracer result.

Rotary Detector: a device used to conduct quick, on-site tests of Microtracers and Rumensin in feed.

When You Choose Rumensin, You Can Trust That It:

- Has better particle-size distribution compared to the 28% to 37% of Monovet that is not suited for feed mixing
- Has higher *in vitro* dissolution than the generic copy
- Has far less variability than the generic copy
- Consists of far less dust than the generic copy

The findings from more than 400 Elanco research studies have made it possible for producers to include Rumensin in ever-changing feed programs and management systems.

The label contains complete use information, including cautions and warnings. Always read, understand and follow the label and use directions.

Caution: Consumption by unapproved species or feeding undiluted may be toxic or fatal. Do not feed to veal calves.

Cattle fed in confinement for slaughter
For improved feed efficiency: Feed 5 to 40 g/ton of monensin (90% DM basis) continuously in a complete feed to provide 50 to 480 mg/hd/d.
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii:* Feed 10 to 40 g/ton of monensin (90% DM basis) continuously to provide 0.14 to 0.42 mg/lb of body weight/d monensin, depending upon severity of challenge, up to a maximum of 480 mg/hd/d.

Growing cattle on pasture or in drylot (stockers, feeders, and dairy and beef replacement heifers)
For increased rate of weight gain: Feed 50 to 200 mg/hd/d of monensin in at least 1.0 lb of Type C medicated feed. Or, after the 5th day, feed 400 mg/hd/d every other day in at least 2.0 lbs of Type C medicated feed. The Type C medicated feed must contain 15 to 400 g/ton of monensin (90% DM basis). Do not self-feed.
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii:* Feed at a rate to provide 0.14 to 0.42 mg/lb of body weight/d monensin, depending upon severity of challenge, up to a maximum of 200 mg/hd/d. The Type C medicated feed must contain 15 to 400 g/ton of monensin (90% DM basis).
Free-choice supplements: Approved supplements must provide not less than 50 nor more than 200 mg/hd/d of monensin.

Calves (excluding veal calves)
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii:* Feed 10 to 200 g/ton to provide 0.14 to 1.0 mg/lb of body weight/d, depending upon severity of challenge, up to a maximum of 200 mg/hd/d. The Type C medicated feed must contain 10 to 200 g/ton of monensin (90% DM basis).

Mature reproducing beef cows
For improved feed efficiency when receiving supplemental feed: Feed continuously at a rate of 50 to 200 mg/hd/d of monensin. Cows on pasture or in drylot must receive a minimum of 1.0 lb of Type C medicated feed/hd/d. Do not self-feed.
For the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii:* Feed at a rate of 0.14 to 0.42 mg/lb of body weight/d, depending upon severity of challenge, up to a maximum of 200 mg/hd/d.

Elanco Rumensin®

[1]Elanco Animal Health. Data on file.
[2]FOI Summary, NADA 200-639.
[3]Elanco Animal Health. Data on file.
[4]United States Pharmacopeia and National Formulary. USP 42-NF 37: Update to Chapter <1236> Solubility Measurements. United States Pharmacopeia Convention, Inc. Rockville, MD. 2019; Supplement 2.
[5]Elanco Animal Health. Data on file.
[6]Elanco Animal Health. Data on file.
[7]Elanco Animal Health. Data on file.
[8]American Feed Industry Association. Chapter 53: Microingredient Mixing. Feed Manufacturing Technology IV.
[9]Elanco Animal Health. Data on file.

PM-US-20-0470(2)

Elanco™