

MONOVET 90- monensin granule
Huvepharma, Inc.

Monovet®90 (monensin Type A Medicated Article)

Front Label

Monovet® 90

(monensin Type A medicated article)

For Animal Feed Only

Do Not Feed Undiluted

Cattle fed in confinement for slaughter:

A: For improved feed efficiency.

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 christensenii*, 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.

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.

NOT FOR HUMAN USE

WARNING:

A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. When mixing and handling **Monovet 90**, 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.

To report adverse effects, access medical information, or obtain additional product information, call 1-877-426-7765. Store at or below 25°C (77°F). Excursions permitted to 37°C (99°F). Not to be used after date printed on gusset of bag.

Restricted Drug (California) - Use Only as Directed

Approved by FDA under ANADA # 200-639

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Distributed by Huvepharma Inc., Peachtree City, GA 30269, USA

Directions for Use

Read All Directions Carefully Before Mixing and Feeding

Active Drug Ingredients: Monensin USP, 90.7 g per pound.

I. Cattle fed in confinement for slaughter:

A. For improved feed efficiency. Feeding Directions: Thoroughly mix **Monovet 90** to make one ton of complete feed that provides

5 to 40 g/ton monensin on a 90% dry matter basis (Table 1). Feed complete feed (5 to 40 g/ton) continuously to growing finishing

beef cattle to provide not less than 50 nor more than 480 mg monensin per head per day. No additional improvement in feed

efficiency has been shown from feeding monensin at levels greater than 30 g/ton (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 40 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 480 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 on the back of the bag

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 15 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 15 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.

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 **Monovet**) 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 **Monovet**. 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 christensenii*, and *Eimeria ninakohlyakimovae*. Feeding Directions: Feed complete feed (20 g/ton) continuously to goats as the sole ration (Table 1). 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 (Table 1).

VII. Type B or C Medicated Feed Mixing Directions (Dry and Liquid):

A. Dry or Liquid

Thoroughly mix the following amounts of **Monovet 90** 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 **Monovet**: 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 Cattle (excluding Dairy Cows), Goat and Calf Feeds

Desired Monensin Concentration in Medicated Feed ^a		Amount of Rumensin 90 Needed per ton	
grams/ton	mg/lb feed	lbs.	grams
5	2.5	0.06	25.00
20	10	0.22	100.02
30	15	0.33	150.03
40	20	0.44	200.04
400	200	4.41	2000.40
1200	600	13.23	6001.19

^a 90% dry matter basis

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

Amount of Monovet 90 needed per ton of Type B, lb ^b	Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^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		
5.51	500	50	22.00	30.00	44.00
		60	26.40	36.00	52.80

15.88	1400	50	7.64	10.42	15.28
		60	9.17	12.50	18.33
88.20	8000	50	1.38	1.88	2.75
		60	1.65	2.25	3.30

^a Amount 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)/90.7 g/lb. Example: 500 g/ton / 90.7 g/lb = 5.51 lb Monovet 90 per ton of Type B

^c 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.

^d 100% dry matter basis

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

Amount of Monovet 90 needed per ton of Type B, lb ^b	Desired monensin concentration in Type B Feed, g/ton; as-fed basis ^c	Desired monensin concentration, g/ton in Component Feed		
		50	200	400
		lb of Type B (as-fed) needed per ton of component feed		
5.51	500	200.00	800.00	1600.00
18.74	1700	58.82	235.29	470.59
44.10	4000	25.00	100.00	200.00
88.20	8000	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 (Desired concentration of monensin in Type B feed, g/ton) / 90.7 g/lb. Example: 500 g/ton / 90.7 g/lb = 5.51 lb Monovet 90 per ton of Type B

^c 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.

KCP-S00042

Rev. 07-2019

Take Time



Principal Display Panel 25 kg Bag Label

Huvepharma

KCP-S00042

Monovet®90

Net Weight: 25 kg

(55.12 lbs)

Do Not Feed Undiluted

(monensin Type A medicated article)



KCP-S000042

Monovet® 90

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Do Not Feed Undiluted

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For Animal Feed Only

MONOVET 90

monensin granule

Product Information

Product Type	VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:23243-0064
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MONENSIN (UNII: 906O0YJ6ZP) (MONENSIN - UNII:906O0YJ6ZP)	MONENSIN	200 g in 1 kg

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
rice bran (UNII: R60QEP13IC)	
calcium carbonate (UNII: H0G9379FGK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-0064-5	25 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200639	07/01/2019	

Labeler - Huvepharma, Inc. (619153559)**Establishment**

Name	Address	ID/FEI	Business Operations
Biovet-AD		645015512	medicated animal feed manufacture, api manufacture, analysis, manufacture, pack, label

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Huvepharma, Inc.