

GAINPRO 10- bambermycins type a medicated article powder
Huvepharma, Inc.

GAINPRO® 10
(bambermycins Type A medicated article)

WITHDRAWAL PERIODS

No withdrawal period is required when used according to labeling.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

INDICATIONS FOR USE:

For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter. For increased rate of weight gain in growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers on pasture.

ACTIVE INGREDIENT:

Bambermycins 10 grams per pound (22 grams per kilogram)

INGREDIENTS:

Roughage products and/or calcium carbonate, dried bambermycins fermentation product, ethoxyquin (a preservative), mineral oil.

MIXING DIRECTIONS AND INDICATIONS FOR USE ON REVERSE SIDE.
FOR USE IN MANUFACTURED FEEDS ONLY.

USER SAFETY WARNING:

Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed

STORAGE:

Store at or below 25°C (77°F), excursions permitted to 40°C (104°F).

Approved by FDA under NADA # 141-034

Net Weight - 50 pounds (22.68 kg)

HUVEPHARMA®

Distributed by:
HUVEPHARMA, INC.
Peachtree City, GA 30269

INDICATIONS FOR USE

| Cattle Classes | Bambermycins g/ton in feed | Bambermycins mg/hd/d | Indications |
|--|----------------------------|-----------------------|---|
| Growing Beef Steers and Heifers Fed in Confinement for Slaughter | 1 - 4 | 10 to 20 mg/hd/day** | Increased rate of weight gain, improved feed efficiency |
| Growing Beef Steers and Heifers on Pasture (Stocker, Feeder, and Slaughter), and Replacement Beef and Dairy Heifers on Pasture | 2 - 80 | 10 to 40 mg/hd/day*** | Increased rate of weight gain |

*Only a single level of bambermycins (e.g. 2 grams bambermycins/ton) can be indicated on a feed tag. A different feed tag must be submitted for each level of bambermycins needed for your complete feeding program.

GROWING BEEF STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER:

****THE APPROVED DOSE IN GROWING BEEF STEERS AND HEIFERS FED IN CONFINEMENT**

FOR SLAUGHTER IS 10 TO 20 MG OF BAMBERMYCINS/HD/DAY. The amount of bambermycins

will range between 1 and 4 grams per ton of feed depending upon the daily feed consumption

of the cattle. The amount of Type A Medicated Article added to the complete ration (Type C

Medicated Feed) must be based on daily feed consumption, the number of animals in the pen

and the level (10-20 mg/hd/day) of bambermycins being fed. From this information the grams

of bambermycins per ton of feed can be calculated in order to fulfill feed assay requirements.

See the following table for conversions from mg/hd/day to g/t.

EXAMPLE OF CONVERTING THE BAMBERMYCINS CATTLE DOSAGE FROM MG/HEAD/DAY TO GRAMS/TON*

| Cattle Weight | | Average Feed Consumption/ Head/Day | Grams Bambermycins/ Ton of Feed | | Mg Bambermycins Fed Daily to each Animal | |
|---------------|-------|------------------------------------|---------------------------------|------|--|------|
| Lbs. | Kg | Lbs. ¹ | Low | High | Low | High |
| 400 | 181.4 | 10.0 | 2.00 | 4.00 | 10.0 | 20.0 |
| 500 | 226.8 | 14.0 | 1.50 | 2.80 | 10.5 | 19.6 |
| 600 | 272.2 | 17.0 | 1.25 | 2.30 | 10.6 | 19.6 |
| 700 | 317.5 | 20.0 | 1.00 | 2.00 | 10.0 | 20.0 |
| 800 | 362.9 | 22.0 | 1.00 | 1.80 | 11.0 | 19.8 |
| 900 | 408.2 | 23.0 | 1.00 | 1.70 | 11.5 | 19.6 |
| 1000 | 453.6 | 24.0 | 1.00 | 1.60 | 12.0 | 19.2 |
| 1100 | 499.0 | 25.0 | 1.00 | 1.60 | 12.5 | 20.0 |
| 1200 | 544.3 | 26.0 | 1.00 | 1.50 | 13.0 | 19.5 |
| 1300 | 589.7 | 27.0 | 1.00 | 1.40 | 13.5 | 18.9 |

*Dosage range is 10 to 20 mg/head/day

¹Assumes as fed *ad libitum* consumption and average daily gain of 2.0 to 3.0 lbs./day

Example Calculation—Amount of GAINPRO®-10 added to feed for a pen of cattle.

Given: Average Weight—800 lbs.; Number in pen—100 hd.; Dosage—20 mg/hd/day; Daily

Feed Consumption—22 lbs./day.

- 100 hd x 20 mg = 2,000 mg or 2 grams bambermycins.

- GAINPRO®-10 contains 10 grams bambermycins/lb., therefore add 0.2 pound of

GAINPRO®-10 to the daily feed for this pen of 100 animals.

- 22 lbs./day x 100 hd = 2,200 lbs. total feed consumption.
- 2 grams bambermycins ÷ 2,200 lbs. = .000909 g/lb.
- .000909 x 2,000 lbs. = 1.82 g bambermycins/ton of feed.

MIXING DIRECTIONS:

It is recommended that GAINPRO®-10 be diluted with a feed ingredient before addition to the final feed. A dilution of 1 part of GAINPRO®-10 and 9 parts feed ingredient is the suggested working intermediate pre-blend. The table below shows examples of GAINPRO®-10 and working intermediate pre-blend addition levels for various commonly used feeds.

| Feed for Growing Beef Steers and Heifers Fed in Confinement for Slaughter | | | |
|---|--------------------------------------|-----------------------|---|
| Bambermycins in Feed g/ton | Making 1 to 9 Intermediate Pre-blend | | 1 to 9 Intermediate Pre-blend lb to be added per ton |
| | GAINPRO®-10 lb | Feed Ingredient lb | |
| 1 | 0.1 | 0.9 | 1 |
| 2 | 0.2 | 1.8 | 2 |
| 3 | 0.3 | 2.7 | 3 |
| 4 | 0.4 | 3.6 | 4 |

Thoroughly mix both working intermediate pre-blend and finished feed to ensure complete and uniform distribution of the GAINPRO®-10.

FEEDING DIRECTIONS:

Feed continuously in a complete feed at the rate of 10-20 mg bambermycins/head/day from the Type C Medicated Feed containing 1-4 g bambermycins/ton.

TYPE B LIQUID MEDICATED FEED INTENDED FOR ADDITION TO DRY FEEDS FOR

GROWING BEEF STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER:

•Type B Liquid Medicated Feed should be in a pH range of 3.8 to 7.5 and should have a moisture content between 30 and 45%.

•Type B Liquid Medicated Feed must be mixed into the dry feed within 8 weeks of manufacture.

•Type B Liquid Medicated Feed can be manufactured containing 40.0 to 800.0 g of bambermycins/

ton. Mixing directions into dry feed are as follows:

Before feeding, the Type B Liquid Medicated Feed must be thoroughly mixed with other feed

materials to make a complete feed (Type C Medicated Feed). Examples of addition rates to

complete feeds are shown in the following table.

| Bambermycins (g/ton) in Type B Liquid Medicated Feed | Addition Rate of Type B Liquid Medicated Feed (lb/ton) to Complete Feed | Bambermycins (g/ton) in Final Complete Feed (Type C Medicated Feed) |
|---|--|--|
| 40.0 | 50.0 | 1.0 |

| | | |
|-------|-------|-----|
| 40.0 | 200.0 | 4.0 |
| 100.0 | 20.0 | 1.0 |
| 100.0 | 80.0 | 4.0 |
| 400.0 | 5.0 | 1.0 |
| 400.0 | 20.0 | 4.0 |
| 800.0 | 2.5 | 1.0 |
| 800.0 | 10.0 | 4.0 |

The complete dry feed (Type C Medicated Feed) may only be fed to growing beef steers and heifers fed in confinement for slaughter and must be fed within one week after mixing.

GROWING BEEF STEERS AND HEIFERS ON PASTURE (STOCKER, FEEDER, AND SLAUGHTER), AND REPLACEMENT BEEF AND DAIRY HEIFERS ON PASTURE:

***THE APPROVED DOSE IN GROWING BEEF STEERS AND HEIFERS ON PASTURE (STOCKER, FEEDER, AND SLAUGHTER), AND REPLACEMENT BEEF AND DAIRY HEIFERS ON PASTURE IS

10 TO 40 MG OF BAMBERMYCINS/HD/DAY. Daily intakes of bambermycins in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

MIXING DIRECTIONS:

It is recommended that GAINPRO®-10 be diluted with a feed ingredient before addition to the supplemental feed. A dilution of 1 part of GAINPRO®-10 and 9 parts feed ingredient is the suggested working intermediate pre-blend. The table below shows examples of GAINPRO®-10 and working intermediate pre-blend addition levels and feeding rates.

| Feed for Growing Beef Steers and Heifers on Pasture (Stocker, Feeder, and Slaughter) and Replacement Beef and Dairy Heifers on Pasture | | | | |
|--|--------------------------------------|--------------------|--|------------------------|
| Bambermycins in Feed g/ton | Making 1 to 9 Intermediate Pre-blend | | 1 to 9 Intermediate Pre-blend lb to be added per ton | Feeding Rate lb/hd/day |
| | GAINPRO®-10 lb | Feed Ingredient lb | | |
| 2 | 0.2 | 1.8 | 2 | 10 |
| 4 | 0.4 | 3.6 | 4 | 5 - 10 |
| 8 | 0.8 | 7.2 | 8 | 2.5 - 10 |
| 20 | 2.0 | 18 | 20 | 1 - 4 |
| 40 | 4.0 | 36 | 40 | 1 - 2 |
| 80 | 8.0 | 72 | 80 | 1 |

Thoroughly mix both working intermediate pre-blend and finished feed to ensure complete and uniform distribution of the GAINPRO®-10.

To manufacture Type B medicated feeds containing 100.0 to 800.0 g/ton bambermycins mix 10 to 80 lbs. of GAINPRO®-10 with 1990 to 1920 lbs. of non-medicated feed.

To manufacture Type C medicated feeds containing 2.0 to 80.0 g/ton bambermycins from

Type B medicated feeds mix:

40 to 1600 lbs. of Type B feed containing 100 g/ton bambermycins with 1960 to 400 lbs.

of non-medicated feed, or

5 to 200 lbs. of Type B feed containing 800 g/ton bambermycins with 1995 to 1800

lbs. of non-medicated feed.

Thoroughly mix both Type B medicated feed and finished feed to ensure complete and uniform distribution of the GAINPRO®-10.

FEEDING DIRECTIONS FOR HAND-FED TYPE C MEDICATED FEED:

Feed continuously on a hand-fed basis at a rate of 10 to 40 mg bambarmycins per head per day. The drug must be contained in 1 to 10 lbs. of supplemental Type C medicated feed containing 2 to 80 g bambarmycins per ton. Daily intakes of bambarmycins in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

TYPE C FREE-CHOICE MEDICATED FEED:

An FDA approved formula must be used to manufacture free-choice medicated feeds containing bambarmycins. Feed mills that use a proprietary formula are required to be licensed.

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ACTIVE INGREDIENT:

Bambermycins 10 grams per pound (22 grams per kilogram)

INGREDIENTS:

Roughage products and/or calcium carbonate, dried bambermycins fermentation product, ethoxyquin (a preservative), mineral oil.

MIXING DIRECTIONS AND INDICATIONS FOR USE ON REVERSE SIDE.

FOR USE IN MANUFACTURED FEEDS ONLY.

USER SAFETY WARNING:

Not for human use. Keep out of reach of children.

Restricted Drug (California) – use only as directed

STORAGE:

Store at or below 25°C (77°F), excursions permitted to 40°C (104°F).

Approved by FDA under NADA # 141-034

Net Weight – 50 pounds (22.68 kg)



Distributed by:
HUIVEPHARMA, INC.
Pacifica City, CA 92088

GAINPRO 10

(bambermycins Type A medicated article)

| | | | |
|--------------------------------|------|-----------------|------|
| Product Type | DRUG | (Source) | 2070 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| BAMBERMYCINS (UNII: PP922A42V2) (BAMBERMYCINS - UNII:PP922A42V2) | BAMBERMYCINS | 22 g in 1 kg |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| MINERAL OIL (UNII: T5L8T28FGP) | |
| ETHOXYQUIN (UNII: 9T1410R4OR) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|--|
| Color | brown ((Off White to Tan)) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:23243-2070-5 | 22.68 kg in 1 BAG | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA | NADA141034 | 08/22/2016 | |

Labeler - Huvepharma, Inc. (619153559)

Registrant - Huvepharma EOOD (552671651)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|---|
| Huvepharma, Inc. | | 883128204 | manufacture, analysis, label, pack, medicated animal feed manufacture |