HEIFERMAX 500- melengestrol acetate liquid Elanco US Inc.

Elanco™

AF0637

HeifermaX™ 500

(melengestrol acetate Type A liquid medicated article)

HEIFERS FED IN CONFINEMENT FOR SLAUGHTER:

For Increased Rate of Weight Gain, Improved Feed Efficiency, and Suppression of Estrus (Heat).

HEIFERS INTENDED FOR BREEDING:

For Suppression of Estrus (Heat).

Each Pound Contains:

Active Drug Ingredient: Melengestrol acetate 500 mg (as melengestrol acetate and its propylene glycol ketal) Inactive Ingredient: Propylene glycol, USP 99.89%

Precautions:

For manufacturing, processing, or repacking. To be mixed with feed prior to animal use.

Use only as directed. Excessive contact with skin should be avoided. Destroy empty container. Do not reuse.

Store at controlled room temperature (20° to 25°C)

Approved by FDA under ANADA # 200-343

Net Weight 40 Pounds (18 kg) (4.627 gal [17.5 L])

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WARNINGS:

Not for human use.

DIRECTIONS FOR USE:

Heifers Fed in Confinement for Slaughter:

HEIFERMAX 500 (melengestrol acetate Type A liquid medicated feed) should be thoroughly mixed in liquid Type C medicated feed which must be fed at 0.5 to 2.0 pounds per head daily to provide 0.25 to 0.5 mg of melengestrol acetate per head per day. Average daily intakes approximating the middle of this range provide the most optimal and economical improvements in rate of weight gain and feed utilization. Constant daily intakes of 0.35 to 0.50 mg per head per day give a high degree of estrus suppression. Levels of 0.25 to 0.35 mg provide a lower but still effective degree of estrus suppression.

Heifers Intended for Breeding:

HEIFERMAX 500 should be thoroughly mixed in the supplement to provide 0.5 mg of melengestrol acetate per head per day.

PRECAUTIONS:

Not effective in steers and spayed heifers.

Heifers Fed in Confinement for Slaughter:

Withdrawal periods of three to five days or more should be avoided to prevent the possibility that the heifers may come into estrus (heat) at loading time.

Heifers Intended for Breeding:

Do not exceed 24 days of feeding of melengestrol acetate to heifers intended for breeding. A reduced conception rate can be expected if heifers are bred at estruses observed within 1 to 12 days after withdrawal of melengestrol acetate, whereas heifers bred at subsequent observed estruses are expected to have normal conception rates.

MIXING DIRECTIONS:

Liquid Type B and C medicated feeds containing melengestrol acetate must have a pH of 4.0 to 8.0 and their labels must bear appropriate mixing directions. Mixing directions for liquid Type B (or C) feeds stored in recirculation tank systems are:

"Recirculate immediately prior to use for no 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 directed in this paragraph even when the Type B (or C) feed is not used." Mixing directions for liquid Type B and C feeds stored in mechanical, air or other agitation-type tank systems are:

"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 directed in this paragraph, even when the Type B (or C) feed is not used."

Intermediate medicated feeds should not be made from HEIFERMAX 500 except as a part of a continuous mixing operation to make a complete liquid Type B (or C) medicated feed.

Thoroughly mix 0.5 to 4 pounds of HEIFERMAX 500 per ton of a non-medicated feed to prepare a Type C medicated feed containing 0.25 to 2.0 grams of melengestrol acetate per ton. The following table may be used as a guide in determining the amount of HEIFERMAX 500 to be added to prepare a ton of Type C medicated feed.

| | | HEIFERMAX 500 Per Ton of Type C Feed | | |
|---|--|---|------------------------------|--|
| Amount of Type C Feed Fed (lb/head/day) | Melengestrol Acetate (mg/head/day) | When Added by Weight (lb) | When Added by Volume (mL) | |
| 0.5 | 0.25 | 2.00 | 876 | |
| 0.5 | 0.30 | 2.40 | 1051 | |
| 0.5 | 0.35 | 2.80 | 1226 | |
| 0.5 | 0.40 | 3.20 | 1402 | |
| 0.5 | 0.45 | 3.60 | 1577 | |
| 0.5 | 0.50 | 4.00 | 1752 | |
| 1.0 | 0.25 | 1.00 | 438 | |
| 1.0 | 0.30 | 1.20 | 526 | |
| 1.0 | 0.35 | 1.40 | 613 | |
| 1.0 | 0.40 | 1.60 | 701 | |
| 1.0 | 0.45 | 1.80 | 788 | |
| 1.0 | 0.50 | 2.00 | 876 | |
| 1.5 | 0.25 | 0.66 | 289 | |
| 1.5 | 0.30 | 0.80 | 350 | |
| 1.5 | 0.35 | 0.93 | 407 | |
| 1.5 | 0.40 | 1.07 | 469 | |
| 1.5 | 0.45 | 1.20 | 526 | |
| 1.5 | 0.50 | 1.33 | 582 | |
| 2.0 | 0.25 | 0.50 | 219 | |
| 2.0 | 0.30 | 0.60 | 263 | |
| 2.0 | 0.35 | 0.70 | 307 | |
| 2.0 | 0.40 | 0.80 | 350 | |
| 2.0 | 0.45 | 0.90 | 394 | |
| 2.0 | 0.50 | 1.00 | 438 | |

Type B medicated feed containing 4 to 10 grams melengestrol acetate per ton may be manufactured by thoroughly mixing 8 to 20 lbs of HEIFERMAX 500 (melengestrol acetate Type A liquid medicated feed) with 1992 to 1980 lbs of non-medicated feed. Labeling for such Type B feed shall contain directions for manufacturing Type C medicated feeds containing 0.25 to 2.0 grams melengestrol acetate per ton (0.125 to 1.0 mg/lb). The Type C medicated feed, containing melengestrol acetate, must be top dressed on grain or roughage or mixed with a complete ration at the rate of 0.5 to 2.0 pounds per head per day. Good manufacturing practice regulations must be adhered to in manufacturing feeds containing HEIFERMAX 500.

Restricted Drug — Use only as Directed (California)

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Distributed by Elanco US Inc., Greenfield, IN 46140, USA

Product of Spain

To report adverse events, access medical information, or to obtain additional product information, call 1-800-428-4441

Approved by FDA under ANADA # 200-343

YL100949B

Principal Display Panel - 40 lb Carton Label

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| | EIFERMAX 5 | | | | | | | |
|--|--|------------|----------------|-------------|------------------------|-----------|------|----------------|
| P | roduct Informa | tion | | | | | | |
| Pr | roduct Type OTC ANIMAL DRUG Item Code (Source) | | NDC:58198-0637 | | | | | |
| Ro | oute of Administra | ation | ORAL | | | | | |
| | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | |
| Ingredient Name | | | | | is of ngth | Strength | | |
| melengestrol acetate (UNII: 4W5HDS3936) (melengestrol - UNII:BX98J4T6JU) | | | melengest | rol acetate | e 500 mg in 0.45 kg | | | |
| | | | | | | | | |
| Packaging | | | | | | | | |
| # | ltem Code | Packa | ge Description | Ма | rketing S [.] | tart Date | Mark | eting End Date |
| 1 | NDC:58198-0637-1 | 1 in 1 CAF | RTON | | | | | |
| _ | | 18 kg in 1 | B 4.11 | | | | | |

| Marketing Information | | | | | | | |
|--|-------------|-------------------------|-----------------------|--|--|--|--|
| Marketing CategoryApplication Number or Monograph Citation | | Marketing Start Date | Marketing End Date | | | | |
| ANADA | ANADA200343 | 09/23/2012 | | | | | |
| | | | | | | | |

Labeler - Elanco US Inc. (966985624)

Revised: 9/2023

Elanco US Inc.