

CYCLEGUARD 500- melengestrol acetate liquid
Huvepharma, Inc

CycleGuard® 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, U.S.P. 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 4° - 25°C (39° - 77°F).

Excursions permitted up to 40°C (104°F).

Approved by FDA under ANADA #200-399

Net Weight 40 Pounds (18 kg)

(4.627gal [17.5 L])

HUVEPHARMA®

KCP-S00037

Version 02 Rev. 02-2022

DIRECTIONS FOR USE:

Heifers Fed in Confinement for Slaughter:

CycleGuard 500 (melengestrol acetate Type A liquid medicated article) 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 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:

CycleGuard 500 should be thoroughly mixed in the supplement to provide 0.5 mg of

melengestrol
acetate per head per day.

WARNINGS: Not for human use. Restricted Drug (California)—Use Only As Directed

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 CycleGuard 500 except as a part of a continuous mixing operation to make a complete liquid Type B or Type C medicated feed.

Thoroughly mix 0.5 to 4 pounds of CycleGuard 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 CycleGuard 500 to be added to prepare a ton of Type C medicated feed.

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

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>.

Approved by FDA under ANADA #200-399

Manufactured For: Huvepharma, Inc
525 Westpark Dr. Suite 230
Peachtree City, GA 30269
1-877-994-4883

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melengestrol acetate liquid

Product Information

Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:23243-0068
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MELENGESTROL ACETATE (UNII: 4W5HDS3936) (MELENGESTROL - UNII: BX98J4T6JU)	MELENGESTROL ACETATE	500 mg in .45 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-0068-1	18 kg in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200399	02/21/2021	

Labeler - Huvepharma, Inc (619153559)

Revised: 5/2022

Huvepharma, Inc