CLINACOX- diclazuril granule Elanco US Inc.

INDICATIONS:

Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati)* and *E. maxima*.

Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*.

Growing Turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis* and *E. meleagrimitis.*

IMPORTANT: MUST BE THOROUGHLY MIXED INTO POULTRY FEEDS BEFORE USE.

DIRECTIONS:

To manufacture a Type C medicated feed directly from the Type A medicated article: Thoroughly mix one pound (1 lb) of CLINACOX (0.2% diclazuril) into each ton of complete feed to provide 0.91 g/ton (1 ppm) of diclazuril (use level). It is recommended that an intermediate mix containing one part CLINACOX and not less than nine parts appropriate feed ingredient be thoroughly mixed before incorporation into the final feed.

To manufacture a Type B medicated feed and then a Type C medicated feed: Thoroughly mix 200 lbs of CLINACOX (0.2% diclazuril) with 1800 lbs unmedicated feed to produce 2000 lbs of Type B medicated feed containing 182 g/ton (200 ppm) diclazuril. Thoroughly mix 10 lbs of the resulting Type B medicated feed with 1990 lbs of unmedicated feed to produce 2000 lbs of Type C medicated feed containing 0.91 g/ton (1 ppm) diclazuril. The resulting Type C medicated feed should be fed continuously as the sole ration.

CAUTION: Do not feed to breeding turkeys.

WITHDRAWAL PERIODS AND RESIDUE WARNINGS

No withdrawal period is required when used according to labeling. Do not feed to birds producing eggs for human consumption.

Adverse Event Reporting: To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Net contents: 25 lbs (11.33 kg) Net contents: 20 kg (44.09 lbs)

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

Not to be used after the date printed on bag.

Restricted Drug (California) - Use Only as Directed

Not for human use.

Approved by FDA under NADA # 140-951

Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Product of China

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YL102389X YL103383X

Principal Display Panel - 25 lbs Bag Label

AF0659

Elanco™

Clinacox 0.2%

(diclazuril Type A medicated article)

ACTIVE DRUG INGREDIENT: Diclazuril, 0.2%

INERT INGREDIENTS: Wheat middlings, calcium carbonate, soybean oil with 0.02% TBHQ (preservative), and silicon dioxide.

Clinacox™ 0.2%

TM

(diclazuril Type A medicated article)

ACTIVE DRUG INGREDIENT: Diclazuril, 0.2% **INERT INGREDIENTS:** Wheat middlings, calcium carbonate, soybean oil with 0.02% TBHQ (preservative), and silicon dioxide.

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Place variable data headers inside this box

Lot number: Use by:

Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Product of China

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WITHDRAWAL PERIODS AND RESIDUE WARNINGS



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Principal Display Panel - 20 kg Bag Label

AF0659

Elanco™

Clinacox 0.2%

(diclazuril Type A medicated article)

ACTIVE DRUG INGREDIENT: Diclazuril, 0.2%

INERT INGREDIENTS: Wheat middlings, calcium carbonate, soybean oil with 0.02% TBHQ (preservative), and silicon dioxide.

Clinacox™ 0.2%

TM

(diclazuril Type A medicated article)

ACTIVE DRUG INGREDIENT: Diclazuril, 0.2% INERT INGREDIENTS: Wheat middlings, calcium carbonate, soybean oil with 0.02% TBHQ (preservative), and silicon dioxide.

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DIRECTIONS:

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YL103383X



CLINACOX

Product Information					
Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:58198- 0659		
Route of Administration	ORAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Diclazuril (UNII: K110K1B1VE) (Diclazuril - UNII:K110K1B1VE)	Diclazuril	0.9 g in 1 kg		

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:58198-0659-1	11.33 kg in 1 BAG				
2	NDC:58198-0659-2	20 kg in 1 BAG				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA	NADA140951	12/04/2001			

Labeler - Elanco US Inc. (966985624)

Revised: 4/2023 Elanco US Inc.