

AMPROL 25 TYPE A MEDICATED ARTICLE- amprolium powder
Huvepharma, Inc.

Approved by FDA under NADA # 012-350

Product 956150

AMPROL® 25%
(amprolium)
Type A Medicated Article

INDICATIONS FOR USE:

AMPROL® 25% (amprolium) Type A medicated article is intended for use in (1) preventing outbreaks of coccidiosis in growing chickens, turkeys, and pheasants and (2) development of active immunity to coccidiosis in replacement chickens. AMPROL 25% is also intended for use in the prevention and treatment of coccidiosis in laying chickens.

WITHDRAWAL PERIODS:

No withdrawal period is required when used according to labeling.

ACTIVE DRUG INGREDIENT: Amprolium. 25%

INGREDIENTS: Corn Gluten Feed and Soybean Oil

STORAGE: Store at or below 25°C (77°F), excursions permitted to 40°C (104°F). Avoid prolonged exposure to high humidity.

SEE DIRECTIONS ON BACK PANEL

Manufactured by:	Huvepharma, Inc.
HUVEPHARMA, INC. St. Louis, MO 63116	525 Westpark Drive, Suite 230
	Peachtree City, GA 30269

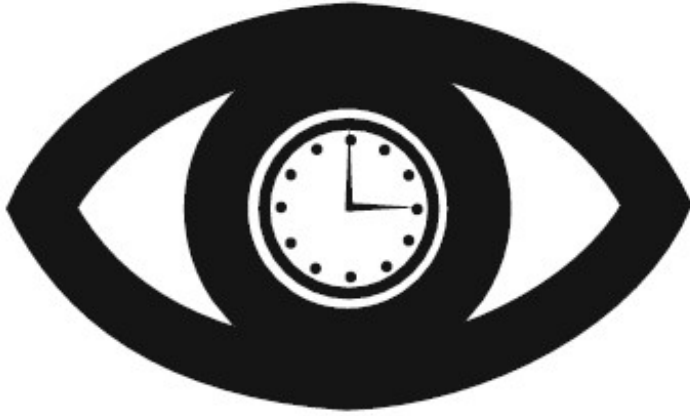
Distributed by:
HUVEPHARMA, INC. Peachtree City, GA 30269

For questions please call 1-877-994-4883

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Net Wt.: 50 lb (22.68 kg)

TAKE TIME



OBSERVE LABEL DIRECTIONS

MIXING DIRECTIONS

AMPROL® 25% (amprolium) Type A medicated article should be thoroughly and evenly mixed in the feed. AMPROL 25% may be used to manufacture a Type C medicated feed in the concentration range of 0.004% to 0.025%. The table below shows the amount of AMPROL 25% to be used in each ton (2000 lb) of feed to obtain desired levels of amprolium in the Type C medicated feed.

To aid in even distribution of AMPROL 25% in the finished feed, prepare a mixture of AMPROL 25% in a portion of complete feed ingredient before mixing into the finished ration. Blend the mixture with the remainder of the finished feed and mix thoroughly.

Feeding level of Amprolium in Type C Medicated Feed	Use This Amount of AMPROL 25% Per Ton
0.004%	5 oz.
0.006%	8 oz
0.008%	10 oz
0.0125%	1 lb
0.0175%	1 lb 6 ½ oz
0.025%	2 lb

AMOUNT AND DIRECTIONS FOR USE

CHICKENS

Broilers:	Prevention: Use 0.0125% amprolium Type C medicated feed continuously for most field conditions as they exist
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under modern management practices. Where severe coccidiosis conditions exists and where immunity is not required, use 0.025% amprolium Type C medicated feed. For field conditions where only *E. tenella* is the major problem, use 0.008%-0.0125% amprolium Type C medicated feed.

Increasing levels of amprolium may not prevent coccidiosis caused by strains of *Eimeria* commonly found to be resistant to Amprolium.

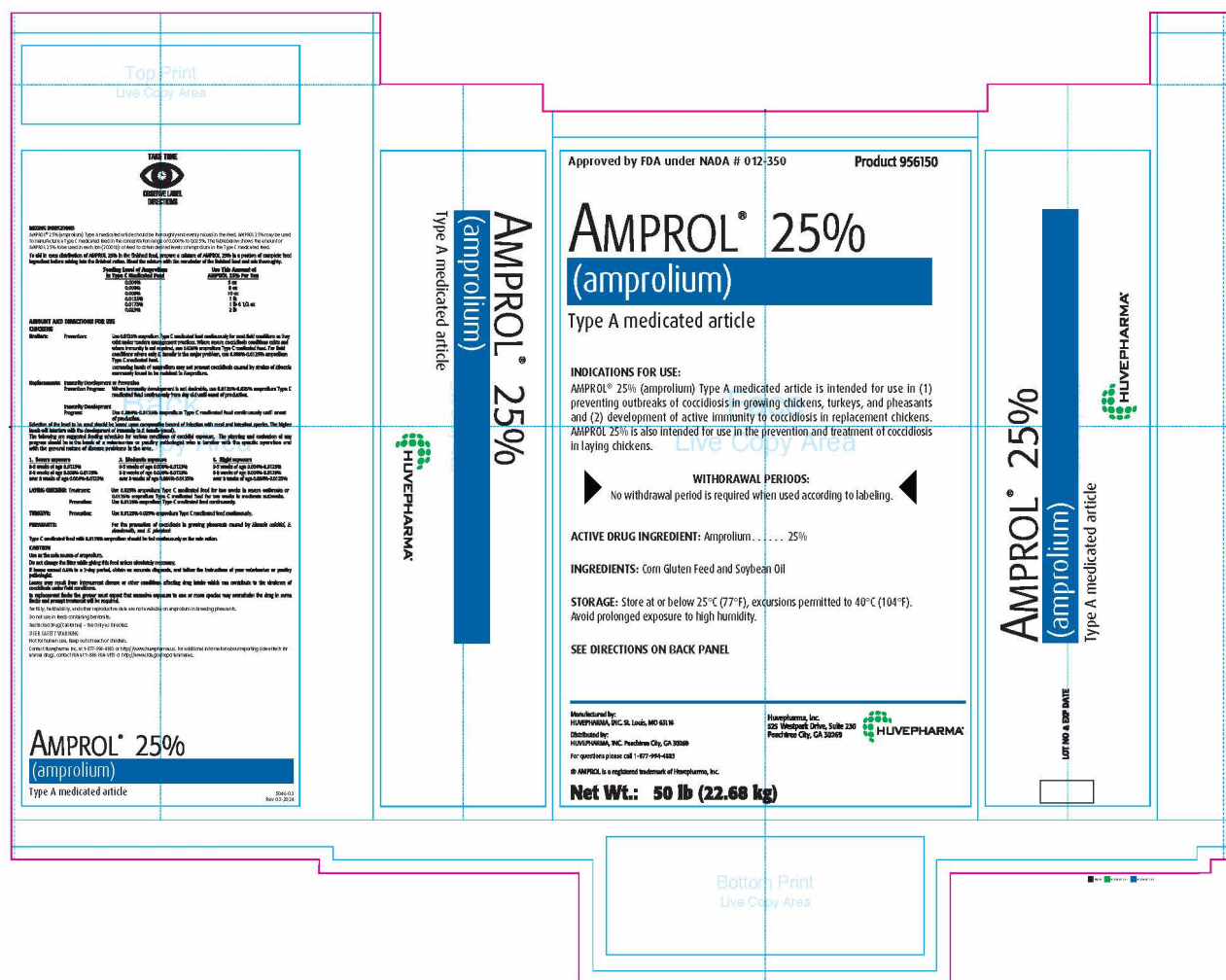
Replacements:	Immunity	Where immunity development is not desirable, use
	Development	0.0125%-0.025% amprolium Type C medicated feed
	or	continuously from day old until onset of production.
	Prevention	
	Prevention	
	Program:	
	Immunity	Use 0.004%-0.0125% amprolium Type C medicated feed
	Development	continuously until onset of production.
	Program:	

Selection of the level to be used should be based upon comparative hazard of infection with cecal and intestinal species. The higher levels will interfere with the development of immunity to *E. tenella* (cecal). The following are suggested feeding schedules for various conditions of coccidial exposure. The planning and evaluation of any program should be in the hands of a veterinarian or poultry pathologist who is familiar with the specific operation and with the general nature of disease problems in the area.

1. Severe exposure	2. Moderate exposure	3. Slight exposure
0-5 weeks of age 0.0125%	0-5 weeks of age 0.008%-0.0125%	0-5 weeks of age 0.004%-0.0125%
5-8 weeks of age 0.008%-0.0125%	5-8 weeks of age 0.006%-0.0125%	5-8 weeks of age 0.004%-0.0125%
over 8 weeks of age 0.004%-0.0125%	over 8 weeks of age 0.004%-0.0125%	over 8 weeks of age 0.004%-0.0125%

LAYING CHICKENS:	Treatment: Use 0.025% amprolium Type C medicated feed for two weeks in severe outbreaks or 0.0125% amprolium Type C medicated feed for two weeks in moderate outbreaks. Prevention: Use 0.0125% amprolium Type C medicated feed continuously.
TURKEYS:	Prevention: Use 0.0125%-0.025% amprolium Type C medicated feed continuously.
PHEASANTS:	For the prevention of coccidiosis in growing pheasants caused by <i>Eimeria colchici</i> , <i>E. duodenalis</i> , and <i>E. phasianii</i> .

Type C medicated feed with 0.0175% amprolium should be fed continuously as the sole



AMPROL 25 TYPE A MEDICATED ARTICLE

amprolium powder

Product Information

Product Type	OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG	Item Code (Source)	NDC:23243-9561
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPROLIUM (UNII: 95CO6N199Q) (AMPROLIUM ION - UNII:H2T307KMZR)	AMPROLIUM	250 g in 1 kg

Inactive Ingredients

Ingredient Name	Strength
AMINO ACIDS, CORN GLUTEN (UNII: 0540V8ZD7V)	
SOYBEAN OIL (UNII: 241ATL177A)	

Product Characteristics

Color	brown ((Light Tan to Brown))	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-9561-5	22.68 kg in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA012350	05/29/2009	

Labeler - Huvepharma, Inc. (619153559)

Registrant - Huvepharma EOOD (552671651)

Establishment

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

