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

AMPROL 25%

BAG FRONT

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

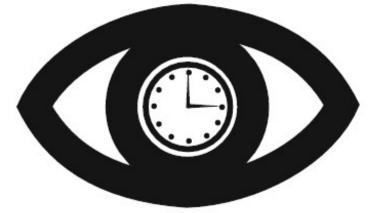
Manufactured by: Huvepharma, Inc., St. Louis, MO 63116 Huvepharma, Inc. 525 Westpark Drive, Suite 230 Peachtree City, GA 30269

Distributed by: Huvepharma, Inc., Peachtree City, GA 30269

® AMPROL is a registered trademark of Huvepharma, Inc.

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 Amproliur | n Use This Amount of |
|----------------------------|---------------------------|
| in Type C Medicated Feed | <u>AMPROL 25% Per Ton</u> |
| 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

| | 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 <i>E. tenella</i> 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 <i>Eimeria</i> commonly |
| | found to be resistant to Amprolium. |
| Replacements: Immunity | Where immunity development is not desirable, use |
| Development | t0.0125%-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 | tcontinuously until onset |
| Program: | of production. |

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%- | 0-5 weeks of age 0.004%- |
| | 0.0125% | 0.0125% |
| 5-8 weeks of age 0.008%- | 5-8 weeks of age 0.006%- | 5-8 weeks of age 0.004%- |
| 0.0125% | 0.0125% | 0.0125% |
| over 8 weeks of age | over 8 weeks of age | over 8 weeks of age |
| 0.004%-0.0125% | 0.004%-0.0125% | 0.004%-0.0125% |

| LAYING | Treatment: Use 0.025% amprolium Type C medicated feed for two |
|-----------|--|
| CHICKENS: | 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, E. duodenalis,</i> and <i>E. phasiani.</i> |

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

ration.

CAUTION

Use as the sole source of amprolium.

Do not change the litter while giving this feed unless absolutely necessary. If losses exceed 0.5% in a 2-day period, obtain an accurate diagnosis, and follow the instructions of your veterinarian or poultry pathologist.

Losses may result from intercurrent disease or other conditions affecting drug intake which can contribute to the virulence of coccidiosis under field conditions.

In replacement flocks the grower must expect that excessive exposure to one or more species may overwhelm the drug in some flocks and prompt treatment will be required. Fertility, hatchability and other reproductive data are not available on amprolium in breeding pheasants.

Do not use in feeds containing bentonite.

Restricted Drug (California) - Use Only as Directed.

USER SAFETY WARNING

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

Contact Huvepharma Inc. at 1-877-994-4883 or http://www.huvepharma.us. For additional information about reporting side effects for

animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

| | | Approved by FDA under NADA # 012-350 Product 956150 |
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| AMPROL* 25% (amprolium) Type A medicated article | | Manahatani Sir HAMMINAR III: CR. Linis, MO GRIIS Batahana Ty: HAMMINAR III: CR. Linis, MO GRIIS Batahana Ty: HAMMINA III: Cr. Addatani Day, CA 32000 For questions please CR1 - 107-194-4883 @ AMMINE is registered instants of Narophana, Inc. Net Wit:: 50 Ib (22.68 kg) |

Amprol 25 Bag Label

AMPROL 25 TYPE A MEDICATED ARTICLE

amprolium powder

| Draducat | Informa | tion | | | | | | | |
|---|---|---|--|-----------------|-------|-------------------------|------|--------------------|-----------------------------------|
| Product | Informa | ition | | | | | | | |
| Product T | уре | OTC TYPE A MEDICATED ARTICLE ANIMAL Item Code (Source) | | | | | | NDC:23243- 9561 | |
| Route of | Administr | ation | ORAL | | | | | | |
| | | | | | | | | | |
| Active Ir | ngredien | t/Active | Moiety | | | | | | |
| Ingredient Name Basis of Strer | | | | | | f Stren | ngth | Strength | |
| AMPROLIU | M (UNII: 950 | CO6N199Q) | (Amprolium Ion - Ui | NII:H2T307KMZR) | А | MPROLIUI | М | | 250 g in 1 kg |
| | | | | | | | | | |
| Inactive | Ingredie | ents | | | | | | | |
| | | | Ingredient Na | me | | | | 3 | Strength |
| AMINO ACI | DS, CORN | GLUTEN (U | NII: 0540V8ZD7V) | | | | | | |
| SOYBEAN | DIL (UNII: 24 | 11ATL177A) | | | | | | | |
| | | | | | | | | | |
| | | | nt Tan to Brown)) | | | Score | | | |
| Color | | | nt Tan to Brown)) | | | Score Size | | | |
| Color Shape Flavor | | | nt Tan to Brown)) | | | | Code | | |
| Product Color Shape Flavor Contains | | | nt Tan to Brown)) | | | Size | Code | | |
| Color Shape Flavor | | | nt Tan to Brown)) | | | Size | Code | | |
| Color Shape Flavor Contains | | | nt Tan to Brown)) | | | Size | Code | | |
| Color Shape Flavor Contains Packagi i | | brown ((Ligł | nt Tan to Brown)) ge Description | Marketing | | Size Imprint | | eting | g End Date |
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| Color Shape Flavor Contains Packagii # Iten | ng n Code 43-9561-5 | Packa 22.68 kg i | ge Description n 1 BAG | | Start | Size Imprint | Mark | | g End Date rketing End Date |
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Labeler - Huvepharma, Inc. (619153559)

Registrant - Huvepharma EOOD (552691651)

Establishment

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

Revised: 12/2022

Huvepharma, Inc.