Amproline® 400 mg/ml

Solution for use in drinking water • **Amprolium [as hydrochloride]**

Composition **Each ml contains:**
Active substance: Amprolium 400.0 mg (equivalent to 452.4 mg of amprolium hydrochloride).
Excipients-Preservative: Sorbic acid (E200) 0.5 mg
Diluent qs 1.0 ml.

Dosage form: Solution for use in drinking water.

Product description: Clear and yellow solution.

Indication
Treatment of intestinal coccidiosis caused by *Eimeria* spp. susceptible to amprolium.

Target sepcies
Chickens (broilers, pullets, layers and breeder hens), turkeys.

Side effects: None known.

Withdrawal periods
Meat and offal: zero days • **Eggs:** zero days.

Contraindications
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

Recommended dosage and mode of administration
For use in drinking water. The posology for each target species is 20 mg amprolium/kg body weight/day (equivalent to 0.5 ml of oral solution/10 kg body weight/day) for 5 to 7 consecutive days. For the preparation of medicated water, the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like age, state of health, breed, and husbandry system. To provide the required amount of veterinary medicinal product in ml/L drinking water the following calculation should be made:*
Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. Medicated drinking water should be replaced every 24 hours. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance. The veterinary medicinal product should not be used in contact with metal pipework or containers.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Expiry date and special storage conditions
Shelf life after 1st opening the immediate packaging, at 25°C: 6 months. **Shelf life after dilution according to directions:** 24 hours. Do not store above 25 °C. Store in a dry place. Protect from direct sunlight. Store in the original container.

Pharmacodynamics
Amprolium is an anticoccidial which belongs to the thiamine analogues family. Amprolium acts by interfering as a competitive antagonist of thiamine within thiamine transport mechanisms. It interferes in the carbohydrate metabolism required for coccidies multiplication and survival. In *in-vitro* studies it was shown that the uptake of thiamine by schizonts of *Eimeria tenella* and by host intestinal cells can occur through passive diffusion or by an active, energy-and pH-dependent process.

* $\frac{\text{0.05 ml of the product/kg body weight} \times \text{average body weight (kg) of the animals to be daily treated} \times \text{number of animals}}{\text{total water consumption (L) of the herd at the previous day}} = \text{ml of oral solution/L of drinking water}$

HUVEPHARMA®

Batch: PBO-000000-0
Mfg: MM/YYYY **Exp:** MM/YYYY
GTIN : 00000000000000

1 L

SOLUTION FOR USE IN DRINKING WATER
CHICKENS • TURKEYS

Amproline® 400 mg/ml Solution for use in drinking water

Amprolium competitively inhibited both systems, however, the parasite was shown to be more sensitive to amprolium than the host. As shown with *Eimeria maxima* inoculated chicken, the administration of Amprolium resulted in a proportion of morphologically abnormal macrogametes and oocysts which may be considered the reason for a reduced sporulation rate.

Pharmacokinetics

Amprolium is weakly absorbed after oral administration. Maximum plasma drug concentration is reached 4 hours later. Amprolium is excreted mainly via faeces.

Environmental properties

Amprolium is very persistent in soil.

Warning and precautions

Special warnings for each target species: As with any antiparasiticide, frequent and repeated use of antiprotozoal agents from the same class can lead to resistance development. As with all anticoccidials, prolonged use may result in the development of resistant strains. Use of anticoccidial drugs having the same mode of action should be avoided due to the development of cross-resistance. In case of detection of lack of efficacy during treatment, communicate it to the competent national authorities. **Special precautions for use in animals:** The product is not intended for a preventive use. This product should be reserved in case of coccidiosis outbreaks due to non-availability of vaccine, in case of lack of efficacy of vaccine and in vaccinated flocks if a severe coccidial challenge is diagnosed before immunity has fully developed. **Special precautions to be taken by the person administering the medicinal product to animals:** This product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways. Avoid all physical contact with the product, including any vapours. Do not eat, drink or smoke whilst handling this product. Wear impervious gloves and protective glasses when handling the product. In the case of contact with skin or eyes, wash the affected area with clean running water immediately and remove any contaminated clothes. If irritation persists, seek medical advice and show the label to the physician. In case of accidental ingestion, rinse the mouth with fresh water, seek medical advice immediately and show the label to the physician. People with known hypersensitivity to amprolium or to sorbic acid should avoid contact with the product. Wash hands and exposed skin after use. **Pregnancy and lactation:** Studies in laboratory animals have not produced any evidence of teratogenic effects. The safety of amprolium has not been established in laying birds. Use only according to the benefit/risk assessment by the responsible veterinarian. **Interactions with medicaments:** Amprolium is a thiamine analogue. Therefore, the efficacy of amprolium may be reduced during a simultaneous administration of products containing vitamin-B complex. **Symptoms and treatment of overdose:** A prolonged use at high doses can produce thiamine deficiency. This deficiency can be compensated for by an appropriate thiamine intake. **Incompatibilities:** In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. **Special precautions for disposal of unused products or waste materials, if any:** Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Packaging available: 1 L, 5 L.

Keep out of reach of children | Jauhkan daripada kanak-kanak
Controlled Medicine | Ubat Terkawal • For animal use only

HUVEPHARMA®

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