

Leaflet + Label

For Veterinary Use Only

AMPROVIL

Oral Solution

Veterinary Anticoccidial

COMPOSITION

It is a clear yellow to pale yellow solution. containing amprolium hydrochloride equivalent to 200 mg of amprolium, and 1 mg methyl paraben as a preservative.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Amprolium is an anticoccidial agent that acts as a competitive thiamine inhibitor in parasite metabolism. It interferes with carbohydrate metabolism, which is essential for the growth and survival of coccidia.

In vitro studies have shown that thiamine uptake by *Eimeria tenella* schizonts and host intestinal cells can occur either by passive diffusion or by an active, energy- and pH-dependent transport mechanism. Amprolium competitively inhibits both pathways, but the parasite has been shown to be more sensitive to amprolium than the host.

Administration of amprolium leads to the formation of morphologically abnormal macrogametes and oocysts, which is considered a possible cause of reduced sporulation rates.

Pharmacokinetic Properties

Following oral administration, absorption is low and maximum concentration is reached after 4 hours. The drug is primarily excreted via feces.

AREA OF USE/INDICATIONS

Used for the treatment of intestinal coccidiosis caused by susceptible *Eimeria* spp. in chickens and turkeys.

USAGE AND DOSAGE

It is administered with drinking water.

20 mg amprolium / kg body weight daily for 5–7 days in chicken and turkeys.

When preparing the medicated water, the body weight of the animals to be treated and their actual daily water consumption must be taken into account. Consumption may vary depending on factors such as age, health status, species, environmental temperature, and husbandry system.

To calculate the amount of veterinary medicinal product (in ml) to be added per liter of drinking water, use the following formula:

$$\frac{0.1 \times \text{Average body weight of the animals to be treated (kg)} \times \text{Number of animals to be treated}}{\text{Amount of water consumed by the animals to be treated on the previous day (liters)}} = \text{Amount of product to be mixed per liter of water (in mL)}$$

Adequate access to the water supply system must be ensured for the animals under treatment to guarantee sufficient water intake. No other sources of drinking water should be available during the treatment period. Medicated drinking water must be replaced every 24 hours.

After the end of the treatment period, the water supply system should be properly cleaned to prevent the intake of sub-therapeutic amounts of the active substance.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

As with other antiparasitic products, frequent and repeated use of products belonging to the same class may lead to the development of resistance.

This product is not intended for use as a preventive measure against infestation.

This product should be considered a reserve treatment, to be used in cases of coccidiosis outbreaks when vaccines are unavailable, ineffective, or when serious coccidial threats are diagnosed in vaccinated flocks before full immunity has developed.

Use during pregnancy: Studies conducted on laboratory animals have not provided any evidence of teratogenic effects.

ADVERSE EFFECTS

Unknown.

DRUG INTERACTIONS

Amprolium is a thiamine analogue. Therefore, concurrent administration with products containing vitamin B complex may reduce the efficacy of amprolium.

Do not use in combination with other products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Prolonged use may lead to thiamine deficiency.

In cases of deficiency, thiamine supplementation should be administered to compensate.

WITHDRAWAL PERIODS

Zero (0) days in chickens and turkeys.

CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to the ingredients.

GENERAL WARNINGS

Consult a veterinarian before use and if any unexpected reactions occur.

Keep out of reach of children and away from foodstuffs.

Do not purchase or use products past their expiry date or with damaged packaging.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON

Avoid all physical contact with the product, including its vapors.

Do not eat, drink, or smoke while handling this product.

Wear waterproof gloves and protective goggles while handling the product.

Selected gloves must comply with EN 374 standard.

In case of skin or eye contact, immediately rinse the affected area with running water and remove contaminated clothing. Seek medical advice if irritation persists and show the label to the doctor.

If accidentally ingested, rinse the mouth with clean water, seek medical advice immediately, and show the label to the doctor.

People known to be hypersensitive to amprolium or any excipients should avoid contact with the product.

Wash hands and exposed skin after use.

STORAGE CONDITIONS AND SHELF LIFE

Before and after opening, it should be stored in the original packaging, protected from light, below 25°C, without refrigeration or freezing.

Shelf life is 2 years. The diluted product should be used within 24 hours.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES

Used product containers and any unused or leftover product must be disposed of according to applicable regulations.

COMMERCIAL PRESENTATION FORM

1 L white HDPE plastic bottles without boxes.

PLACE OF SALE AND CONDITIONS

Sold by veterinary prescription in pharmacies and veterinary clinics (VHP).

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MARKETING AUTHORIZATION DATE AND NO: 12.06.2006 – 016/0026

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

VİLSAN Veteriner İlaçları Tic. Ve San. A.Ş.

Balıkhisar Mah. Balıkhisar Köy içi Küme Evleri No:765A Akyurt/Ankara /Türkiye

MANUFACTURER COMPANY

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Made in Türkiye