

Veterinary Package Insert

TP-AMPRO 200MG/G POWDER (20% Amprolium Hydrochloride)

PRODUCT DESCRIPTION

White to slightly yellow colour powder, which contains 200mg of amprolium hydrochloride (177mg of amprolium) per gram in sachet.

PHARMACODYNAMICS & PHARMACOKINETICS

Amprolium is an anticoccidial agent that acts as a competitive inhibitor of thiamine in the metabolism of the parasite and interferes with the formation of the oocyst wall.

It is little absorbed after oral administration, reaching the maximum concentration between 1 and 4 hours. It is mainly eliminated by stool.

INDICATION

Poultry: Treatment of coccidiosis caused by Eimeria spp. sensitive to amprolium.

TARGETED SPECIES

Poultry: chickens (broilers, future laying and breeding pullets and laying hens) and turkeys.

RECOMMENDED DOSAGE AND ADMINISTRATION

For oral administration via the drinking water.

In all species the recommended dosage is:

30 mg amprolium / kg p.v. / day (equivalent to 169.5 mg of medicine / kg p.v. / day) for 5 - 7 days.

For the preparation of medicated water, the weight of the animals to be treated and the actual consumption of water must be taken into account. Water consumption depends on various factors such as age, clinical situation of the animals, breed or breeding system.

According to the recommended dose, the number and weight of the birds that should receive the treatment, the exact daily dose of medication will be calculated applying the following formula:

$$\frac{\text{g of medication}}{\text{litre of drinking water}} = \frac{\text{dose of active substance (mg/kg p.v. / day)} \times \text{average weight of animals (kg)}}{\text{mg of active substance in g of medicine (mg/g)} \times \text{average water consumption (litre/day)}}$$

The medicated water will be the only source of water during the treatment; all animals must be guaranteed access to medicated water.

CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substance or to any excipient.

WARNINGS & PRECAUTIONS.

Special precautions for use in animals:

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to amprolium should avoid contact with the veterinary medicinal product.

Handle the medication with care to avoid inhalation of dust, as well as contact with the skin and eyes, during its incorporation into the water taking specific precautions:

- Take appropriate measures to prevent the spread of dust during the incorporation of the drug into drinking water.
- Use a dust mask, gloves, work coveralls and approved safety glasses.
- If skin or eye exposure occurs accidentally, wash immediately with plenty of water.
- Do not smoke, eat or drink while handling the medication.

INTERACTIONS WITH OTHER MEDICATIONS

Amprolium is an analogue of thiamine. Simultaneous administration with vitamin B complexes could reduce their effectiveness.

PREGNANCY AND LACTATION

Contraindications during the laying have not been established.

ADVERSE EFFECTS

None known.

OVERDOSE & TREATMENT

Prolonged use can cause thiamine deficiency. If symptoms appear, thiamin should be given.

WITHDRAWAL PERIOD

Meat: 0 days

Eggs: 0 days

MAXIMUM RESIDUAL LIMIT (MRL)

Substance / Drug Definition of residues in which MRL was set	Food	Maximum Residue Limits (MRLs) in food µg/kg
Amprolium (1-4 amino-2-n- propyl-5- (pyrimidinylmethyl)- 2-picolinium chloride hydrochloride)	Muscle	500
	Liver	1000
	Egg	4000

STORAGE CONDITION

Store below 30° C. Protect from direct sunlight.

SHELF LIFE

3 years.

After 1st opening, reconstitution or dilution, use within
24 hours.

PACKING

200g

600g

1kg

THYE PHARMA SDN. BHD.

(manufacturer & product registration holder)

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