

Metatoltra 2.5% w/v For Animal Use Only

Oral Solution

CONTENT: Each ml contains:

Toltrazuril.....25mg

PRODUCT DESCRIPTION: A clear colorless to yellowish solution.

PHARMACODYNAMICS:

Toltrazuril is an anticoccidial of the triazinetrione group, active against *Eimeria* spp. Toltrazuril induces changes in the fine structure of the developmental stages of coccidia. These are caused primarily by swelling of the endoplasmic reticulum and of the Golgi apparatus, abnormal changes to the perinuclear space and disturbances in cell division. Toltrazuril causes a decrease in the activity of respiratory chain enzymes in the parasites.

PHARMACOKINETICS:

Toltrazuril undergoes at least 50% absorption in poultry. The highest concentrations are to be found in the liver and kidneys of the poultry. The active substance is broken down rapidly. The main metabolite is toltrazuril sulfone.

INDICATION:

For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens : *E. acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. tenella*.

Turkeys : *E. adenoides* and *E. meleagrimitis*.

DOSAGE & ADMINISTRATION:

For oral administration via the drinking water.

In order to ensure administration of a correct dose, accurately determine the body weight of the animals.

The dose is 7 mg toltrazuril per kg body weight (bw) per day (= 0.28 ml [product] per kg bw per day).

Treatment is carried out on two consecutive days.

The medicinal product should be administered either continuously over 24 hours or for one period of 8 hours per day – for 2 consecutive days.

Medicated drinking water should be refreshed every 24 hours.

The dosage should be based on the current, actual drinking water intake of the birds, because this varies depending on the bird species, on the age, state of health and intended use of the birds, and depending on the housing conditions (e.g. different ambient temperature, different lighting regime).

In the case of continuous treatment over 24 hours, the volume of the product to be mixed into the drinking water for the birds to be treated is calculated according to the following formula:

Volume of the product required per liter drinking water:

$$\frac{0.28 \text{ ml [product] per kg bw per day} \times \text{Average bw (kg) of the birds to be treated}}{\text{Average drinking water intake in liters over 24 hours per bird}} = \text{X ml [product] per liter drinking water}$$

Total volume of the product required per day (24 h):

The calculated volume (x ml [product] per liter) must be multiplied by the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the volume of the product to be mixed into the drinking water for the birds to be treated is calculated according to the following formula:

Volume of the product required per liter drinking water:

$$\frac{0.28 \text{ ml [product] per kg bw per day} \times \text{Average bw (kg) of the birds to be treated}}{\text{Average drinking water intake in liters over 8 hours per bird}} = \text{y ml [product] per liter drinking water}$$

Total volume of the product required for a treatment period of 8 hours:

The calculated volume (y ml [product] per liter) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

The appropriate volume of solution must be added daily to the drinking water while stirring.

If volumes of between 1 and 4 ml product are added per liter drinking water, solubility is guaranteed over the period of treatment.

In order to ensure that all the birds drink water evenly, sufficient space must be made available at the waterer.

Free-range birds must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.

Predilution and the administration through a dosing pump (proportioner) are not recommended.

Use preferably a bulk tank.

CONTRAINDICATIONS:

Do not use in birds with hypersensitivity to the active substance or to any of the excipients.

WARNINGS / PRECAUTIONS:

Hygiene measures help to reduce the risk of coccidiosis. It is therefore recommended that attention be paid during treatment to hygiene in confinement buildings, particularly in terms of general cleanliness and moisture reduction.

It is recommended to treat all animals in a pen. For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

Special precautions for use in animals

As with any antiparasitic agent, frequent and repeated use of antiprotozoal agents from the same class of active substances and underdosing due to underestimation of the live weight can lead to the development of resistance. It is important to keep to the recommended dose in order to minimize the risk of resistance.

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

Wear synthetic rubber gloves when handling the product.

Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

The veterinary medicinal product is an alkaline solution.

In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.

Do not eat, drink or smoke during use.

Wash hands after use.

DRUGS INTERACTIONS: None.

PREGNANCY AND LACTATION: Not applicable

ADVERSE EFFECTS: None known.

OVERDOSE AND TREATMENT:

A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

STORAGE CONDITIONS: Store at room temperature below 30°C. Protect from heat and sunlight exposure.

WITHDRAWAL PERIOD(S):

Chickens:

Meat and offal: 16 days

Turkeys:

Meat and offal: 16 days

Not authorized for use in poultry producing eggs for human consumption.

Do not use in pullets beyond the 15th week of life.

DOSAGE FORMS AND PACKAGING AVAILABLE: 1 Liter Oral Solution packed into HDPE bottle.

DATE OF REVISION OF PACKAGE INSERT: 15 February 2018.

TO BE PRESCRIBED BY REGISTERED VETERINARY SURGEONS ONLY



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