

Veterinary Package Insert

TP-Tolzuril 50mg/ml Solution

PRODUCT DESCRIPTION

A light yellow to yellow colour solution, which contains 50mg/ml of toltrazuril in 1L bottle.

PHARMACODYNAMICS & PHARMACOKINETICS

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.

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, caused by infections with various species of *Eimeria*:
Chickens: *E. acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. tenella*.

TARGET SPECIES

Chickens (broilers, pullets and breeders).

RECOMMENDED DOSAGE AND ADMINISTRATION

The dose is 7 mg toltrazuril per kg body weight (bw) per day (= 0.14 ml [product] per kg bw per day). Treatment is carried out on 2 consecutive days.

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

TP-Tolzuril 50mg/ml Solution 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.

- i. 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 Litre drinking

water:

$$\frac{0.14 \text{ ml [product]}}{\text{per kg bw per day}} \times \frac{\text{Average bw (kg) of the birds to be treated}}{\text{Litre drinking water}} = x \text{ ml [product] per Litre drinking water}$$

Average drinking water intake in Litres over 24 hours per bird

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

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

- ii. 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 Litre drinking

water:

$$\frac{0.14 \text{ ml [product]}}{\text{per kg bw per day}} \times \frac{\text{Average bw (kg) of the birds to be treated}}{\text{Litre drinking water}} = y \text{ ml [product] per Litre drinking water}$$

Average drinking water intake in Litres over 8 hours per bird

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

The calculated volume (y ml [product] per Litre) 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.

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 sub-therapeutic doses, particularly if liable to promote the development of resistance.

Pre-dilution 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.

Warning for target species

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.

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 under-dosing due to under-estimation 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.

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 totrazuril 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.

INTERACTIONS WITH OTHER MEDICATIONS

None.

PREGNANCY AND LACTATION

Not applicable. See section on withdrawal period.

ADVERSE EFFECTS

None known.

OVERDOSE & 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.

WITHDRAWAL PERIOD

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.

MAXIMUM RESIDUAL LIMIT (MRL)

Chicken

Muscle: 100 µg/kg

Skin + fat: 200 µg/kg

Liver: 600 µg/kg

Kidney: 400 µg/kg

Not for use in animals from which eggs are produced for human consumption.

STORAGE CONDITION

Store in a cool, dry place (below 30°C). Protect from sunlight. Keep container tightly closed.

SHELF LIFE

3 years.

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

THYE PHARMA SDN. BHD.

No.2 Lorong Industri Ringan Permatang
Tinggi 8,
Kawasan Industri Ringan Permatang Tinggi,
14000 Bukit Mertajam,
Pulau Pinang.

Revised November 2018