

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dozuril 25 mg/ml solution for use in drinking water for chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance

Toltrazuril 25 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for use in drinking water.

Clear colourless to brown solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (pullets and breeders)

4.2 Indications for use, specifying the target species

Treatment of coccidiosis in pullets and broiler breeders.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Good hygiene can reduce the risk of coccidiosis. It is therefore recommended that any deficiencies in husbandry should be addressed in addition to treatment. Poultry houses should be kept clean and dry.

It is recommended that all individuals in the group are treated.

For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

4.5 Special precautions for use

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 minimise the risk of resistance.

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

Avoid skin and eye contact with the product.

Wear personal protective clothing, including synthetic rubber gloves when handling the product.

Wash any splashes from skin or eyes immediately with water.

Wash hands and any exposed skin after use.

Do not eat, drink or smoke whilst using the product.

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

4.6 Adverse reactions (frequency and seriousness)

Not known.

4.7 Use during pregnancy, lactation or lay

None.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration: Orally via the drinking water.

Dosage: 7 mg per kg of bodyweight per day for 2 consecutive days, orally, this corresponds to 28 ml of oral solution per 100 kg of bodyweight per day or 1.4 ml of the product per litre of drinking water, based on a water consumption of 1 litre per 5 kg bodyweight.

This medicinal product should be administered either continuously over 48 hours, or for one 8 hour period per day for 2 consecutive days.

The total weight of the treated animals and the daily water consumption must be accurately calculated.

The consumption of water may vary depending in particular on the clinical condition, the ambient temperature, the lighting program, the drinking system used, the age and breed. If the water consumption is more or less than the above standards, the concentration of the medicinal product in the drinking water should be adjusted accordingly.

Use appropriate and properly calibrated dosing equipment. Medicated water should be the only drinking source.

The medicated water is only usable for 24 hours and should be made freshly every day.

Dilutions more concentrated than 3:1,000 (3 ml of product to 1 litre drinking water) may result in precipitation. Predilution and the administration through a dosing pump (proportioner) are not recommended. Use preferably a bulk tank.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The first signs of intolerance such as reduced water intake were observed beyond 5 times the recommended dose.

4.11 Withdrawal period(s)

Meat and offal: 16 days.

Eggs: Not for use in birds producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals, triazines

ATCVet Code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinone derivative anticoccidial. At parasite level, toltrazuril decreases the enzymatic activity of the respiratory chain, causing inflammation of the endoplasmic reticulum and Golgi apparatus, perinuclear space modifications and alteration of division of the nucleus.

It is active against coccidia of the genus Eimeria. It is active against all intracellular development stages including schizogony (asexual multiplication) and gametogony (sexual stage).

5.2 Pharmacokinetic properties

In poultry, toltrazuril is absorbed at a rate of at least 50%. The active substance is rapidly metabolized. The main metabolite is the toltrazuril sulfone.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine

Macrogol 300

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.

Shelf-life after first opening the immediate packaging: 3 months.

Shelf-life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

1 litre high-density polyethylene bottles with high-density polyethylene screw cap and removable polyethylene sealing disk.

5 litre high-density polyethylene barrels with high-density polyethylene screw cap and removable polyethylene sealing disk.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10791/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th May 2012
Date of latest renewal: 11th August 2017

10 DATE OF REVISION OF THE TEXT

August 2017