PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

HDPE bottle, can

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dozuril CT 25 mg/ml solution for use in drinking water for chickens and turkeys.

2. COMPOSITION

Toltrazuril 25 mg/ml

Clear colourless to yellow-green solution for use in drinking water.

3. PACKAGE SIZE

1 L, 5 L.

4. TARGET SPECIES

Chickens (pullets and breeders), turkey.

5. INDICATIONS FOR USE

Indications for use

Treatment of coccidiosis 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*.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:
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 safe use in the target species:

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.
This veterinary medicinal product should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the veterinary medicinal product, like 'coccidiostats' and 'histomonostats'.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be irritating to the skin, eye or mucous membranes.
Avoid skin and eye contact, including hand-to-eye contact and hand-to-mouth contact.
Wear personal protective clothing, including synthetic rubber gloves when handling the veterinary medicinal product.
Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the veterinary medicinal product.
Wash hands after use.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to the active substance and/or macrogol 300 should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may be harmful for the unborn child. Pregnant women and women intending to conceive should avoid contact with the veterinary medicinal product.

Laying birds/Fertility:
The safety of the veterinary medicinal product has not been established during the breeding period. Laboratory studies in rats and rabbits have shown evidence of repro- and embryotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
Combination of the veterinary medicinal product with antibiotics may result in reduced water intake in turkeys. The concomitant administration of other substances to the drinking water should be avoided.

Overdose:
A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 5 times the recommended dose.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.

The dose is 7 mg toltrazuril per kg body weight (BW) per day (= 0.28 ml veterinary medicinal product per kg BW per day). Treatment is carried out on two consecutive days.
The veterinary medicinal product should be administered either continuously over 24 hours or for one period of 8 hours per day - for 2 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 veterinary medicinal product to be mixed into the drinking water for the birds to be treated is calculated according to the following formula:

Volume of the veterinary medicinal product required per liter drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product/ kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean water consumption (litre) per animal over 24 hours}} = \text{x ml veterinary medicinal product per litre of drinking water}$$

Total volume of the veterinary medicinal product required per day (24 h):
The calculated volume (x ml veterinary medicinal product per litre) 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 veterinary medicinal product to be mixed into the drinking water for the birds to be treated is calculated according to the following formula:

Volume of the veterinary medicinal product required per liter drinking water:

$$\frac{\text{0.28 ml veterinary medicinal product/ kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean water consumption (litre) per animal over 8 hours}} = \text{y ml veterinary medicinal product per litre of drinking water}$$

Total volume of the veterinary medicinal product required for a treatment period of 8 hours:
The calculated volume (y ml veterinary medicinal 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 subtherapeutic doses, particularly if liable to promote the development of resistance.

Dilutions more concentrated than 3:1,000 (3 ml of veterinary medicinal 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 16 days.
Not for use in birds producing or intended to produce eggs for human consumption. Do not use withing 6 weeks before the start of the laying period.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

1 litre HDPE bottles.
5 litre HDPE cans.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma France
23, Rue du Prieuré
Saint Herblon
FR-44150 Vair sur Loire

Dopharma B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer

18. OTHER INFORMATION

<**Other information**>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp.

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions: 24 hours.
Once opened, use by …

21. BATCH NUMBER

Lot