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

HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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).

5. INDICATIONS FOR USE

Indications for use

Treatment of coccidiosis in pullets and broiler breeders.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
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.

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 minimise 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 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 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.

Overdose:
The first signs of intolerance such as reduced water intake were observed beyond 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 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
Administration: Orally via the drinking water.

7 mg toltrazuril 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 veterinary medicinal product per litre of drinking water, based on a water consumption of 1 litre per 5 kg bodyweight.
This veterinary medicinal product should be administered either continuously over 48 hours, or for one 8 hour period per day for 2 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

The total weight of the treated animals and the daily water consumption must be accurately calculated.
The intake of medicated water depends on the clinical condition of the animals, the ambient temperature, the lighting program, the drinking system used, the age and breed. In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.
The use of suitably calibrated measuring equipment is recommended. 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 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 within 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 bottles
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 {mm/yyyy}

Once opened use by…

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions in drinking water: 24 hours.

21. BATCH NUMBER

Lot {number}