ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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

Excipients:

Qualitative composition of excipients and other constituents
Trolamine
Macrogol 300

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets and breeders)

3.2 Indications for use for each target species

Treatment of coccidiosis in pullets and broiler breeders.

3.3 Contraindications

None.

3.4 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.

3.5 Special precautions for use

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See section "Contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administration: Orally via the drinking water.
Dosage: 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.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51BC01

4.2 Pharmacodynamics

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).

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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