ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dozuril CT 25 mg/ml solution for use in drinking water for chickens and turkeys (DE, IT, NL, PL)
Cozuril CT 25 mg/ml solution for use in drinking water for chickens and turkeys (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:
Toltrazuril 25 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 300
Trolamine

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets and breeders), turkeys

3.2 Indications for use for each target species

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*.

3.3 Contraindications

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

3.4 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.

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 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.

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

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.

3.9 Administration routes and dosage

In drinking water use.

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

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.
Medicated drinking water should be refreshed every 24 hours.

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.

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

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.

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 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.

4.3 Pharmacokinetics

Toltrazuril undergoes at least 50% absorption in poultry after oral administration. 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.

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: bottle: 4 years.
Shelf life of the veterinary medicinal product as packaged for sale: jerrycan: 3 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 bottle with high-density polyethylene screw cap, fitted with a tamper evident seal-ring and removable polyethylene sealing disk.
5 litre high-density polyethylene jerrycan with high-density polyethylene screw cap and fitted with a tamper evident seal-ring.

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).