ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys

[AT]
Baycox Direct 25 mg/ml, solution for use in drinking water for chickens and turkeys

[IT]
Baycox PT 25", 25 mg / ml oral solution be administered in drinking water for broilers and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution 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.
Colourless to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broilers, pullets and breeders) and turkeys.

4.2 Indications for use, specifying the target species

For the treatment of coccidiosis in chickens and turkeys, 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*.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

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.

4.5 Special precautions for use

Special precautions for use in animals

As with any anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.

If resistance is present it should be considered to use another antiprotozoal from another class/mechanism of action.

This VMP 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".

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

The veterinary medicinal product is a strongly alkaline solution and should not be administered undiluted.

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

People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Wear synthetic rubber gloves when handling the product.
Contact with skin and mucous membranes should be avoided.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable, see section 4.11, Withdrawal periods.

4.8 Interaction with other medicinal products and other forms of interaction

Combination of the product with antibiotics may result in reduced water intake in turkeys. The concomitant administration of other substances to the drinking water should be avoided.

4.9 Amounts to be administered and administration route

For oral administration via the drinking water.
In order to ensure administration of a correct dose, the total weight of the treated animals and the daily water consumption must be accurately calculated.

The dose is 7 mg toltrazuril per kg body weight (bw) per day (= 0.28 ml [product] per kg bw per day).
Treatment is carried out on two consecutive days.
The medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.
In case an automatic dose dispenser is used the medicinal product should be administered 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 animals, because this varies depending on the animal species, on the age, state of health and intended use of the animals, 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 product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of the product required per litre drinking water:

0.28 ml [product] per kg bw per day	x	Average bw (kg) of the animals to be treated	=	x ml [product] per litre drinking water
Average drinking water intake in litres over 24 hours per animal				

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

Volume of the product required per litre drinking water:

0.28 ml [product] per kg bw per day	x	Average bw (kg) of the animals to be treated	=	y ml [product] per litre drinking water
Average drinking water intake in litres over 8 hours per animal				

Total volume of the product required for a treatment period of 8 hours:
The calculated volume (y ml [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.

If volumes of between 1 and 4 ml product are added per litre drinking water, solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals 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.

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

A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

4.11 Withdrawal periods

Chickens:
Meat and offal: 16 days

Turkeys:
Meat and offal: 16 days

Eggs: 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoal, triazine
ATCvet code: QP51AJ01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

After oral administration, toltrazuril undergoes at least 50% absorption in poultry. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 200
Trolamine

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life after first opening the immediate packaging: 3 months

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the product.

Shelf life after dilution or reconstitution according to directions: 24 hours

6.4. Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

100 ml (available in cartons of 1 x 100 ml) white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}>
Date of last renewal: <{DD/MM/YYYY}>

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.