Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Toltrazuril	25.0 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear colourless to brown solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (pullets and breeders).

4.2 Indications for use, specifying the target species

Treatment of coccidiosis in pullets and broiler breeders.

4.3 Contraindications

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

4.4 Special warnings for each target species

As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances.

4.5 Special precautions for use

i) Special precautions for use in animals

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

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

This product is an alkaline solution-contact with skin and mucous membranes should be avoided. Personal protective equipment consisting of gloves and goggles should be worn when handling this product. Wash any splashes from skin or eyes immediately with water. In case of irritation of eyes or skin after exposure, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known sensitivity to toltrazuril, or any excipient, should avoid contact with this product.
Do not eat, drink or smoke while handling the product.

iii) Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration (in drinking water)
The recommended dose rate is 7 mg per kg of body weight (equivalent to 28 ml of medicinal product per 100 kg of body weight or 1.4 ml of the product per liter of drinking water based on a water consumption of 1 litre per 5 kg body weight) daily given for 2 consecutive days.
This 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 consumption of water may vary depending in particular on the clinical condition, the ambient temperature, the lighting program, the drinking system used, the age and breed. If the water consumption is more or less than the above standards, the concentration of the medicinal product in the drinking water should be adjusted accordingly.
Use appropriate and properly calibrated dosing equipment. 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 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.
After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal Period(s)

Meat and offal : 16 days.
Eggs: Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of onset of laying

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals, triazines
ATCVet Code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinone derivative anticoccidial; its mode of action is unknown. It is active against coccidia of the genus Eimeria. It is active against all intracellular development stages schizogony (asexual multiplication) and gametogony (sexual stage).

5.2 Pharmacokinetic properties

In poultry, toltrazuril is absorbed at a rate of at least 50 %. The active substance is rapidly metabolized. The main metabolite is Toltrazuril sulfone.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Macrogol 300

6.2 Incompatibilities

Do not mix with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years
Shelf-life after dilution according to directions: 24 hours
Shelf-life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.
Barcelones
26 (Pla del Ramassa)
Les Franqueses del Valles
Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10665/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th July 2012

Date of last renewal: 1st March 2017

10 DATE OF REVISION OF THE TEXT

March 2017