[Version 9.1, 11/2024]

ANNEX I

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Trolamine	
Macrogol 300	

Clear colourless to brown solution

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets and chickens for reproduction)

3.2 Indications for use for each target species

Treatment of Coccidiosis in pullets and Broiler Breeders.

3.3 Contraindication

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

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the 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 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.

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

This veterinary medicinal 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 veterinary medicinal 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 the veterinary medicinal product.
Do not eat, drink or smoke while handling 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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable

3.8 Interactions with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

In drinking water use.
The recommended dose rate is 7 mg per kg of body weight (equivalent to 28 ml of the veterinary medicinal product per 100 kg of body weight or 1.4 ml of the veterinary medicinal product per liter of drinking water based on a water consumption of 1 liter per 5 kg body weight) daily given for 2 consecutive days.

This veterinary medicinal product should be administered either continuously over 48 hours, or for one 8 hours period per day for 2 consecutive days
To ensure the correct dosage, total weight of the treated animals and the daily water consumption should be determined as accurately as possible.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 veterinary 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 the 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.
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.

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; 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).

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

Do not mix with any other veterinary medicinal products.

5.2 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

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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. 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).

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

VIA ADHESIVE ON 1 L AND 5 L BOTTLES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substance:
Toltrazuril 25.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Trolamine	
Macrogol 300	

Clear colourless to brown solution

3. PACKAGE SIZE

1 litre
5 litre

4. TARGET SPECIES

Chickens (pullets and chickens for reproduction)

5. INDICATIONS FOR USE

Indications for use

Treatment of Coccidiosis in pullets and Broiler Breeders.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:

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

Special precautions for safe use in the 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 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.

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

This veterinary medicinal 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 veterinary medicinal 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 the veterinary medicinal product.
Do not eat, drink or smoke while handling the veterinary medicinal product.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

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

Major incompatibilities:

Do not mix with any 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<or its local representative> using the contact details on this label, or via your national reporting system: {national system details}

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.

The recommended dose rate is 7 mg per kg of body weight (equivalent to 28 ml of the veterinary medicinal product per 100 kg of body weight or 1.4 ml of the veterinary medicinal product per liter of drinking water based on a water consumption of 1 liter per 5 kg body weight) daily given for 2 consecutive days,
This veterinary medicinal product should be administered either continuously over 48 hours, or for one 8 hours period per day for 2 consecutive days
To ensure the correct dosage, total weight of the treated animals and the daily water consumption should be determined as accurately as possible.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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 veterinary 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 the veterinary medicinal product to 1 litre drinking water) may result in precipitation. Predilution is not recommended.
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.

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 or pharmacist 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 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

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>

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 manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

LABORATORIOS CALIER, S.A. [AT, BG, DE, EE, EL, ES, FR, HU, IE, IT, LT, LV, PL]
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona, Spain
Tel.: +34 (0) 938495133
pharmacovigilance@calier.es

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra
Portugal
Telf: +351 219248140
farmacovigilancia@calier.pt

Manufacturer responsible for batch release:

LABORATORIOS CALIER S.A.
C. Barcelonès, 26
Polígono Industrial del Ramassà

08520 Les Franqueses del Vallès
Barcelona. Spain

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once broached/opened, use by ….
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}