[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zuritol 50 mg/ml oral suspension for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Toltrazuril..... 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Sodium docusate	
Bentonite	
Xanthan Gum (E-415)	
Propylene glycol (E-1520)	
Citric acid, anhydrous	
Simethicone emulsion	
Purified water	

White or yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pig (Piglet, 3-5 days old).

3.2 Indications for use for each target species

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Isospora suis*.

3.3 Contraindications

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

3.4 Special warnings

As with any antiparasiticide, frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

It is recommended to treat all animals in a pen.

Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may cause irritation if it comes into contact with the skin or eyes.

Avoid skin and eye contact with the veterinary medicinal product.

Wash hands and exposed skin after use.

Wash any splashes from skin or eyes immediately with water.

Do not eat, drink or smoke while using 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 immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known, e.g there is no interaction in combination with iron supplementation.

3.9 Administration routes and dosage

Oral use.

Individual animal treatment.

Treat each pig on day 3-5 of life with a single oral dose of 20 mg toltrazuril per kg bodyweight corresponding to 0.4 ml oral suspension per kg bodyweight.

Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The oral suspension must be shaken before use.

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

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

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

No signs of intolerance were observed in piglets up to threefold overdose.

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: 77 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCVet code:

QP51BC01

4.2. Pharmacodynamics

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Isospora*. It is acting against all intracellular development stages of coccidia of the merogony (asexual multiplication) and gamogony (sexual phase). All stages are destroyed, thus the mode of action is coccidiocidal.

4.3. Pharmacokinetics

After oral administration toltrazuril is slowly absorbed with a bioavailability of ≥ 70%. The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a half-life elimination time around 3 days. The major route of excretion is via the faeces.

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: 6 months. Discard unused material.

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

High density polyethylene bottles with a white high density polyethylene screw cap containing 250 ml and 1000 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

VIA ADHESIVE ON 250 ML AND 1000 ML BOTTLES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zuritol 50 mg/ml oral suspension for pigs

2. COMPOSITION

Each ml contains:
Active substance:

Toltrazuril..... 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Sodium docusate	
Bentonite	
Xanthan Gum (E-415)	
Propylene glycol (E-1520)	
Citric acid, anhydrous	
Simethicone emulsion	
Purified water	

White or yellowish oral suspension.

3. PACKAGE SIZE

250 ml
1000 ml

4. TARGET SPECIES

Pig (Piglet, 3-5 days old).

5. INDICATIONS FOR USE

Indications for use

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Isospora suis*.

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 any antiparasiticide, frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

It is recommended to treat all animals in a pen.

Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Special precautions for safe use in the target species:

Not applicable.

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

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may cause irritation if it comes into contact with the skin or eyes.

Avoid skin and eye contact with the veterinary medicinal product.

Wash hands and exposed skin after use.

Wash any splashes from skin or eyes immediately with water.

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

Interactions with other medicinal products and other forms of interaction:

None known, e.g there is no interaction in combination with iron supplementation.

Overdose:

No signs of intolerance were observed in piglets up to threefold overdose.

Major incompatibilities:

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

8. 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

Oral use.
Individual animal treatment.
Treat each pig on day 3-5 of life with a single oral dose of 20 mg toltrazuril per kg bodyweight corresponding to 0.4 ml oral suspension per kg bodyweight.
Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The oral suspension must be shaken before use.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.
To ensure a correct dosage, body weight should be determined as accurately as possible.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 77 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the reach and sight of children.

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

High density polyethylene bottles with a white high density polyethylene screw cap containing 250 ml and 1000 ml.

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, CY, 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: 6 months

21. BATCH NUMBER

Lot {number}