

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:

Sodium benzoate (E211) 2.1 mg

Sodium propionate (E281) 2.1 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension

White or yellowish suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Pig (Piglet, 3-5 days old).

4.2 Indications for use, specifying the 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*.

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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 this product.

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

Avoid skin and eye contact with the 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 product.

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 interactions

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

4.9 Amounts to be administered and administration route

For oral administration.

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.

The weight of animals should be accurately determined before administration.

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

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

4.11 Withdrawal period(s)

Meat and offal: 77 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides & repellents:
Antiprotozoals. Triazinetrione group
ATCVet Code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Isoospora*. 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.

5.2 Pharmacokinetic particulars

After oral administration toltrazuril is slowly absorbed with a bioavailability of $\geq 70\%$. 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E-211)
Sodium propionate (E-281)
Sodium docusate
Bentonite
Xanthan Gum (E-415)

Propylene glycol (E-1520)
Citric acid, anhydrous
Simethicone emulsion
Purified water

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: 4 years
Shelf-life after first opening the immediate packaging: 6 months. Discard unused material.

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

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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8 MARKETING AUTHORISATION NUMBER(S)

VPA10665/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2013

Date of last renewal: 7th September 2018

10 DATE OF REVISION OF THE TEXT

September 2018