

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of oral suspension contains:

Active substance:

Toltrazuril	50	mg
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Excipients:

Sodium benzoate (E211)	2.1	mg
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Sodium propionate (E281)	2.1	mg
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For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

Thick white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (calves on dairy farms).

4.2 Indications for use, specifying the target species

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

4.3 Contraindications

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

For environmental reasons:

Do not use in calves weighing more than 80 kg body weight.

Do not use in fattening units such as veal or beef calves.

For more details see sections 4.5, other precautions and section 5, environmental properties.

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 calves in a pen.

Hygienic measures may reduce the risk of bovine 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

Wash any splashes from skin or eyes immediately with water.

Other precautions

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life > 1 year) and mobile in soil and to be toxic to plants. In order to prevent any adverse effects on plants and possible contamination of groundwater, manure from treated calves must not be spread onto land without dilution with manure from untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land.

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.

4.9 Amounts to be administered and administration route

For oral use.

Each animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.

The ready-to-use oral suspension must be shaken before use.

For the treatment of a group of animals of the same breed and same or similar age, the dosing should be done according to the heaviest animal of this group.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

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

A threefold overdose is well tolerated by calves without signs of intolerance.

4.11 Withdrawal period(s)

Meat and offal: 63 days.

Not authorised for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, antiprotozoals, agents against protozoal diseases, triazines, toltrazuril.

ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (C_{max} = 41.4 mg/l) was observed between 6.00 and 48 hours (median 18 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (59.5 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is *via* the faeces.

5.3 Environmental properties

The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a persistent (half-life >1 year) and mobile compound and has adverse effects on both the growth and emergence of plants. Given the persistent properties of ponazuril, repeated spreading of manure from treated animals may lead to an accumulation in the soil and consequently a risk to plants. The accumulation of ponazuril in soil together with its mobility also leads to a risk of leaching to groundwater. See sections 4.3 and 4.5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Propylene glycol
Docusate sodium
Simeticone emulsion
Aluminium magnesium silicate
Citric acid monohydrate
Xanthan gum
Water, purified

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: 3 years.
Shelf-life after first opening the immediate packaging: 1 year.

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

Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 250 ml of oral suspension in a box.
Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 1000 ml of oral suspension.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Krka, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8 MARKETING AUTHORISATION NUMBER(S)

VPA10774/007/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 November 2013
Date of last renewal: 15 November 2018

10 DATE OF REVISION OF THE TEXT

December 2018