SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolracol 50 mg/ml oral suspension for pigs, cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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
Propylene glycol	
Docusate sodium	
Simeticone emulsion	
Aluminium magnesium silicate	
Citric acid monohydrate	
Xanthan gum	
Water, purified	

Thick white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (Piglets 3 - 5 days old).
Cattle (calves on dairy farms).
Sheep (lambs).

3.2 Indications for use for each target species

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

Cattle:
For the prevention of clinical signs of coccidiosis and reduction of oocyst 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*.

Sheep:
For the prevention of clinical signs of coccidiosis and reduction of oocyst shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

3.3 Contraindications

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

Cattle (for environmental reasons):
Do not use in calves weighing more than 80 kg bodyweight.
Do not use in veal or beef calves.
For more details see sections 3.5 (Special precautions for the protection of the environment) and section 4 (Environmental properties).

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 with regard to dryness and cleanliness. To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period. Treatment during an outbreak will be of limited value for the individual animal, because of damage to the small intestine having already occurred. 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:

People with known sensitivity to toltrazuril or any of the excipients should avoid contact with this veterinary medicinal product.
Do not eat, drink or smoke while using the veterinary medicinal product.
Avoid skin and eye contact with the veterinary medicinal product.
Wash any splashes from skin or eyes immediately with water.

Special precautions for the protection of the environment:

In order to prevent any adverse effects on plants and possible contamination of groundwater, manure from treated calves must be not be spread onto land without dilution with manure from untreated cattle. Manure from treated calves must be diluted with at least 3 times the weight of manure from untreated cattle before it can be spread onto land.
Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from treated animals should only be applied to the same piece of land every third year.

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 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The oral suspension must be shaken before use.
To ensure a correct dosage, 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.

Pigs:
Individual animal treatment.
Each piglet should be treated on day 3 to 5 of life with a single oral dose of 20 mg toltrazuril per kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

Cattle:
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.

If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or over-dosing.

Sheep:
Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or over-dosing.

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

No signs of intolerance were reported in healthy piglets and calves after oral administration of threefold overdose. In lambs, no signs of overdose have been observed with threefold overdose at a single treatment and twofold overdose at treatment on two consecutive days.

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

Pigs:
Meat and offal: 77 days.

Cattle:
Meat and offal: 63 days.
Milk: Not authorised for use in animals producing milk for human consumption.

Sheep:
Meat and offal: 42 days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QP51BC01

4.2 Pharmacodynamics

Toltrazuril is a triazinon derivative. It acts against coccidia of the genera *Eimeria* and *Cystoisospora.* 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.

4.3 Pharmacokinetics

Pigs:
After oral administration of the veterinary medicinal product in pigs, toltrazuril is slowly absorbed with a bioavailability of ≥ 70%. The maximum concentration (C_{max}) of toltrazuril is 14 µg/ml and is obtained after around 30 h after a single oral dose of 20 mg/kg bw. The main metabolite is characterized 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.

Cattle:
After oral administration of the veterinary medicinal product in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (C_{max} = 41.4 mg/L) was observed between 6.00 and 48 hours (mean 19 hours) following a single oral dose of 15 mg/bw. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.7 days (64.15 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is via the faeces.

Sheep:
After oral administration of the veterinary medicinal product in lambs, toltrazuril is slowly absorbed. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration (C_{max} = 64.6 mg/L) was observed between 12 and 120 hours (mean 27 hours) following a single oral dose of 20 mg/bw. The elimination of toltrazuril is slow with an elimination half-life time of up to 9 days (mean 5 days). The major route of excretion is via the faeces.

Environmental properties

The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a very 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.

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

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

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.

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.

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

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER

Vm 01656/4068

8. DATE OF FIRST AUTHORISATION

20 November 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 08 March 2026