1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of oral suspension 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).

3.2 Indications for use for each target species

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 - 5 days) 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.

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:

Wash any splashes from skin or eyes immediately with water.

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 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.
Each piglet to be treated on day 3 to 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 outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

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

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

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 acts 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 maximum concentration (C_{max}) of toltrazuril is 14 µg/ml and is obtained after around 30 h. 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.

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 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

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER(S)

VPA10774/007/001

8. DATE OF FIRST AUTHORISATION

24/09/2010

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

20/04/2026

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).