1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for pigs (BE, DK, DE, IE, RO, SI)
Toltarox VET 50 mg/ml oral suspension for pigs (FI, SE)

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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).

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg of toltrazuril.

3. PACKAGE SIZE

250 ml

4. TARGET SPECIES

Pigs (Piglets 3 – 5 days old).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
The oral suspension must be shaken before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 77 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 1 year.
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER/ IMMEDIATE PACKAGE

LABEL 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg of toltrazuril.

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Pigs (Piglets 3 – 5 days old).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
The oral suspension must be shaken before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 77 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 1 year.
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg of toltrazuril.

3. TARGET SPECIES

Pigs (Piglets 3 – 5 days old).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

The oral suspension must be shaken before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 77 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 1 year.
Once opened, use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Toltarox 50 mg/ml oral suspension for pigs

2. Composition

Each ml of oral suspension contains:

Active substances:
Toltrazuril 50 mg

Excipients:
Sodium benzoate (E211) 2.1 mg
Sodium propionate (E281) 2.1 mg

Thick white suspension.

3. Target species

Pigs (Piglets 3 – 5 days old).

4. Indications for use

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*.

5. Contraindications

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

6. 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.

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.

Interaction with other medicinal products and other forms of interaction:
None known, e.g. there is no interaction in combination with iron supplementation.

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

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

7. 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 in this package leaflet, 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 at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Oral use.
Individual animal treatment.
Due to 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.

10. Withdrawal periods

Meat and offal: 77 days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp. The expiry date refers to the last day of that month.

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

12. 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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Toltarox is available in bottles of 250 ml and 1000 ml.
The 250 ml bottle is supplied in a box.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse events:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Tel:

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information