**PARTICULARS TO APPEAR ON THE OUTER PACKAGE/IMMEDIATE PACKAGE**

**BOX 250 ml/LABEL 1000 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for pigs (Belgium, Denmark, Germany, Ireland, Netherlands, Romania, Slovenia, United Kingdom)
Toltarox vet 50 mg/ml oral suspension for pigs (Finland, Sweden)
Toltrazuril

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of thick white suspension contains 50 mg of toltrazuril with 2.1 mg of sodium benzoate (E211) and 2.1 mg of sodium propionate (E281).

## 3. PHARMACEUTICAL FORM

Oral suspension.

## 4. PACKAGE SIZE

250 ml
1000 ml

## 5. TARGET SPECIES

Pigs (Piglet 3 – 5 days old).

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

## 8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 77 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

The oral suspension must be shaken before use.

## 10. EXPIRY DATE

EXP:

Once opened, use within 6 months.
Once opened, use by…

## 11. SPECIAL STORAGE CONDITIONS

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Lot:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL 250 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for pigs (Belgium, Denmark, Germany, Ireland, Netherlands, Romania, Slovenia, United Kingdom)
Toltarox vet 50 mg/ml oral suspension for pigs (Finland, Sweden)
Toltrazuril

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of thick white suspension contains 50 mg of toltrazuril with 2.1 mg of sodium benzoate (E211) and 2.1 mg of sodium propionate (E281).

## 3. PHARMACEUTICAL FORM

Oral suspension.

## 4. PACKAGE SIZE

250 ml

## 5. TARGET SPECIES

Pigs (Piglet 3 – 5 days old).

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

## 8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 77 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

The oral suspension must be shaken before use.

## 10. EXPIRY DATE

EXP:
Once opened, use within 6 months.

Once opened, use by…

## 11. SPECIAL STORAGE CONDITIONS

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE THE SIGHT AND REACH OF CHILDREN"

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Lot:

**PACKAGE LEAFLET FOR:**

**Toltarox 50 mg/ml oral suspension for pigs**
**Toltarox vet 50 mg/ml oral suspension for pigs**

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toltarox 50 mg/ml oral suspension for pigs (Belgium, Denmark, Germany, Ireland, Netherlands, Romania, Slovenia, United Kingdom)
Toltarox vet 50 mg/ml oral suspension for pigs (Finland, Sweden)
Toltrazuril

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml of thick white suspension contains 50 mg of toltrazuril with 2.1 mg of sodium benzoate (E211) and 2.1 mg of sodium propionate (E281).

## 4. INDICATION(S)

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. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pigs (Piglet 3 – 5 days old).

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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

For 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 PERIOD

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 packaging after {EXP}. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 6 months.

## 12. SPECIAL WARNING(S)

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.

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

Overdose (symptoms, emergency procedures, antidotes), if necessary
A threefold overdose is well tolerated by healthy piglets without signs of intolerance.

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

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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

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.

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