SUMMARY OF PRODUCT CHARACTERISTICS

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)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of oral suspension contains:

Active substance:
Toltrazuril 50 mg

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

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

Pigs (Piglet 3 – 5 days old).

4.2 Indications for use, specifying the 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*.

4.3 Contraindications

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

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.

4.5 Special precautions for use

Special precautions for use in animals

None known.

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.

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 interaction

None known, e.g. there is no interaction in combination with iron supplementation.

4.9 Amounts to be administered and administration route

For 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.

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

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

4.11 Withdrawal period(s)

Meat and offal: 77 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

After oral administration toltrazuril is slowly absorbed with a bioavailability of ≥ 70%. The maximum concentration (Cmax) of toltrazuril is of 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.

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 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: 12 months.

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 product 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

Vm 01656/4034

9. DATE OF FIRST AUTHORISATION

27 September 2011

10. DATE OF REVISION OF THE TEXT

August 2015

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

09 September 2015