PARTICULARS TO APPEAR ON THE OUTER PACKAGE/IMMEDIATE PACKAGE

BOX 250 ml/LABEL 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of thick white suspension contains 50 mg of toltrazuril.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

250 ml
1000 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

	Pigs	Cattle	Sheep
Meat and offal:	77 days	63 days	42 days
Milk:	/	Not authorised for use in animals producing milk for human consumption	

9. SPECIAL WARNING(S), IF NECESSARY

The oral suspension must be shaken before use.

10. EXPIRY DATE

EXP:
Once opened, use within 1 year.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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 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)

Vm 01656/4068

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of thick white suspension contains 50 mg of toltrazuril.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

	Pigs	Cattle	Sheep
Meat and offal:	77 days	63 days	42 days
Milk:	/	Not authorised for use in animals producing milk for human consumption	

9. SPECIAL WARNING(S), IF NECESSARY

The oral suspension must be shaken before use.

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

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Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4068

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET:

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

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

Marketing authorisation holder:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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*.

5. CONTRAINDICATIONS

Do not use cases of known hypersensitivity to the active substance or 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.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

The oral suspension must be shaken before use.
To ensure administration of a correct dose, 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.

10. WITHDRAWAL PERIOD(S)

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.

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: 1 year.

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.
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.

Other precautions

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life > 1 year) and mobile in soil and to be toxic to 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
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.

Interaction with other medicinal products and other forms of interaction

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

Overdose (symptoms, emergency procedures, 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.

User warnings
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 product.
Avoid skin and eye contact with the product.
Wash any splashes from skin or eyes immediately with water.

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

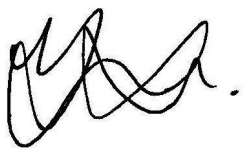
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Tolracol 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.



Approved: 03 September 2019