SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevazuril 50 mg/ml, oral suspension for Piglets and Calves.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Toltrazuril .....50.0 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
Docusate sodium	
Aluminium magnesium silicate	
Xanthan gum	
Propylene glycol	
Citric acid monohydrate	
Simeticone emulsion (containing sorbic acid)	
Water purified	

White homogeneous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (Piglets 3 - 5 days old).
Cattle (calves on dairy farms).

3.2 Indications for use for each target species

Piglets:
For the prevention of clinical signs of cystoisosporosis in neonatal piglets on farms with a confirmed history of cystoisosporosis caused by *Cystoisospora suis*.

Calves:
For the prevention of clinical signs of cystoisosporosis and reduction of coccidia shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of cystoisosporosis, caused by *Eimeria bovis* or *Eimeria zuernii*.

3.3 Contraindications

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

Cattle (for environmental reasons):
Do not use in calves weighing more than 80 kg bodyweight.
Do not use in fattening units such as veal or beef calves.
For more details, see section 3.5, precautions for the protection of the environment.

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.
It is recommended to treat all piglets in a litter and all calves in a pen.
Hygienic measures may reduce the risk of porcine and bovine cystoisosporosis. It is therefore, recommended to concomitantly improve the hygiene conditions in the concerned facility, particularly by increasing dryness and cleanliness.
To alter the course of an established clinical coccidial infection in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.
Wash hands after product administration.
People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
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.
In order to prevent any adverse effects on plants and possible contamination of groundwater, manure from treated calves must not be spread onto land without dilution with manure from toltrazuril untreated cattle. Manure from treated calves must be diluted with at least 3 times the weight of manure from toltrazuril untreated cattle before it can be spread onto land.

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3.6 Adverse events

Cattle, pigs: 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 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.
There is no interaction in combination with iron supplementation.

3.9 Administration routes and dosage

Oral use.
Shake well before use.

Piglets:
Individual animal treatment.
Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

Due to the small volumes required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

Calves:
Each calf should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3 ml oral suspension per 10 kg body weight.
If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

A threefold overdose is well tolerated without adverse clinical signs.

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:
Pigs (piglets): 77 days.
Cattle (calves): 63 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51AJ01

4.2 Pharmacodynamics

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus Isospora and Eimeria. It is acting against all intracellular development stages of coccidia: merogony (asexual multiplication) and gamogony (sexual phase). All stages are destroyed, thus the mode of action is coccidiocidal.

4.3 Pharmacokinetics

Piglets:
After oral administration, toltrazuril is slowly absorbed with a bioavailability of 70%. The maximum concentration (Cmax) of toltrazuril is of 8.9 mg/L and is obtained after around 24 h. The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a terminal half-life elimination time around 76 hours. The major route of excretion is via the faeces.
Calves:
After oral administration toltrazuril is slowly absorbed.
The maximum concentration (Cmax) toltrazuril is of 36.3 mg/L and is obtained after around 36 h.
The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a terminal half-life time of around 96.4 hours. The major route of excretion is via the faeces.

Environmental properties
The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a persistent (half-life > l year) and mobile compound and has adverse effects on both the growth and emergence of 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 to together with its mobility also leads to a risk of leaching to groundwater. See sections 3.3 and 3.5.

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: 2 years

Shelf-life after first opening the vial: 6 months.

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

Nature of immediate packaging:
High density polyethylene bottle
Polyethylene tamper evident screw cap with a polyethylene seal (100 ml and 250 ml bottle)
Polypropylene tamper evident screw cap with a polyethylene seal (1 L bottle)

Pack sizes:
Cardboard box of 1 bottle of 100 ml
Cardboard box of 1 bottle of 250 ml
1-litre bottle
250 ml bottle.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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

Ceva Animal Health Ltd

Explorer House, Mercury Park

Wycombe Lane, Wooburn Green

High Wycombe

Buckinghamshire

HP10 0HH

United Kingdom

7. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/5075

8. DATE OF FIRST AUTHORISATION

25 June 2010

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

September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 22 December 2024