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:
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.
White homogeneous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

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

Calves:
For the prevention of clinical signs of coccidiosis and reduction of coccidia 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*.

4.3 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 4.5, other precautions and section 5, environmental properties.

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.
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 coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly 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.

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.
Wash hands after product administration.
People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

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.
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.

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.
There is no interaction in combination with iron supplementation.

4.9 Amounts to be administered and administration route

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.
For the treatment of a group of animals of the same breed and same or similar age, the dosing should be done according to the heaviest animal of this group.

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

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

A threefold overdose is well tolerated without adverse clinical signs.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, triazines, toltrazuril
ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus Isospora and Eimeria. It isacting 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.

5.2 Pharmacokinetic particulars

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 hour. 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 hours.
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 > I 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 together with its mobility also leads to a risk of leaching to groundwater. See sections 4.3 and 4.5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium propionate (E281)
Sodium benzoate (E211)
Docusate sodium
Aluminium magnesium silicate
Xanthan gum
Propylene glycol
Citric acid monohydrate
Simeticone emulsion (containing sorbic acid)
Water purified

6.2 Major 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: 2 years.
Shelf-life after first opening the immediate packaging: 6 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

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 size
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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2010 Date of last renewal: 24th April 2015

10 DATE OF REVISION OF THE TEXT

May 2018