PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box of 1 vial of 100 ml, Cardboard box of 1 vial of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevazuril 50 mg/ml, oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains: toltrazuril 50 mg.

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

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

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

EXP:
Once opened, use by: __/____/___

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

13. 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

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5075

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

(100 ml and 250 ml labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevazuril 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: toltrazuril 50 mg.

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

EXP:
Once opened use by __/__/__

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cevazuril 50 mg/ml, oral suspension for piglets and calves.

2. Composition

Each ml contains:
Active substance:
Toltrazuril: 50.0 mg
Excipients:
Sodium benzoate (E211): 2.1 mg
Sodium propionate (E281): 2.1 mg

White homogeneous suspension

3. Target species

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

4. Indications for use

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*.

5. Contraindications

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

Catte (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 sections “Special precautions for the protection of the Environment” and "Environmental properties".

6. 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.

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.

Pregnancy and lactation:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
None known.
There is no interaction in combination with iron supplementation.

Overdose:
A threefold overdose is well tolerated without adverse clinical signs.

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

7. Adverse events

Cattle, pigs:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date stated on the label after Exp. The
expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 6 months.

This veterinary medicinal product does not require any special storage conditions.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5075

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing Authorisation Holder and contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel. 01628 334056
email technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

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 together with its mobility also leads to a risk of leaching to groundwater. See sections 5. Contraindications and 6. Special precautions for the protection of the environment.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

1 litre and 250 ml containers

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevazuril 50 mg/ml, oral suspension for piglets and calves.

2. COMPOSITION

Each ml contains:
Active substance:
Toltrazuril: 50.0 mg
Excipients:
Sodium benzoate (E211): 2.1 mg
Sodium propionate (E281): 2.1 mg

White homogeneous suspension

3. PACKAGE SIZE

1L
250ml

4. TARGET SPECIES

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

5. INDICATIONS FOR USE

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*.

6. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Catte (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 sections “Special precautions for the protection of the Environment” and "Environmental properties".

7. 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.

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.

Pregnancy and lactation
Not applicable.

Interaction with other medicinal products and other forms of interaction
None known.
There is no interaction in combination with iron supplementation.

Overdose
A threefold overdose is well tolerated without adverse clinical signs.

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

8. ADVERSE EVENTS

Cattle, pigs:
None known
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

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

12. 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 label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.

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

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5075

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.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

17. CONTACT DETAILS

Marketing Authorisation Holder and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane

Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel. 01628 334056
email technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

18. OTHER INFORMATION

POM-V

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 together with its mobility also leads to a risk of leaching to groundwater. See sections 6. Contraindications and 7. Special precautions for the protection of the environment.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

20. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 month by: ____/____/____

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved 22 December 2024