ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 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

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. {MM/YYYY}
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

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/3040

15. BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 ml
Vial of 250 ml

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

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. {mm/yyyy}
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 IMMEDIATE PACKAGE 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

1 ml contains: Active substance: 50 mg of toltrazuril. Excipients; 2.1 mg of sodium benzoate (E211) and 2.1 mg of sodium propionate (E281).
White homogeneous suspension.

3. PACKAGE SIZE

1 L
250 ml

4. TARGET SPECIES

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

5. INDICATIONS FOR USE

Indications for use
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*.

6. CONTRAINDICATIONS

Contraindications
Do not use in cases of 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 sections "Special precautions for the protection of the environment" and section “Environmental properties”.

7. SPECIAL WARNINGS

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 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.

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medicinal 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.

Interactions 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

Adverse events
Cattle, pigs: None known.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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:
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

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.
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 a correct dosage, body weight should be determined as accurately as possible.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
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 or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/3040

Pack sizes:
Cardboard box of 1 vial of 100 ml
Cardboard box of 1 vial of 250 ml
1-litre bottle
250 ml vial
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

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: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10, av. de La Ballastière, 33500 Libourne, France.

Gavin Hall

Approved 22 December 2024

18. OTHER INFORMATION

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. {mm/yyyy}
Once opened, use within 6 months by ___/___/___
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.

21. BATCH NUMBER

Lot:

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

4. Indications for use

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*.

5. Contraindications

Do not use in cases of 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 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.

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medicinal 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.

Interactions 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 veterinary medicinal 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:
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.
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 a correct dosage, 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 or household waste.
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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database
(https://medicines.health.europa.eu/veterinary)

14. Marketing authorisation numbers and pack sizes

Vm 15052/3040

Pack sizes:
Cardboard box of 1 vial of 100 ml
Cardboard box of 1 vial of 250 ml
1-litre bottle
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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: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10, av. de La Ballastière, 33500 Libourne, France.

17. Other information

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.