ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box of 1 bottle of 100 ml
Cardboard box of 1 bottle of 250 ml
Label of 100 ml bottle
Label of 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: toltrazuril 50 mg.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Piglets and calves.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
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.
[Not required on the immediate label].

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.
[Not required on the immediate label].

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4054

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 1 litre bottle
Label of 250 ml bottle
[Label with no outer carton nor package leaflet]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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).

3. PHARMACEUTICAL FORM

Oral suspension
White homogeneous suspension

4. PACKAGE SIZE

1 L
250 ml

5. TARGET SPECIES

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

6. INDICATION(S)

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*.

7. METHOD AND ROUTE(S) 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 administration of a correct dose, body weight should be determined as accurately as possible.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

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 sections "Other precautions" and "Environmental properties".

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..

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.

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.

Interactions

None known.
There is no interaction in combination with iron supplementation.

Overdose (symptoms, emergency procedures, antidotes)

A threefold overdose is well tolerated without adverse clinical signs.

Incompatibilities

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

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 "Contraindications" and "Other precautions".

10. EXPIRY DATE

EXP:
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.
Once opened, use within 6 months by ___/___/___

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4054

17. MANUFACTURER'S BATCH NUMBER

Lot:

Other information

Date on which this label was last approved

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.

B. PACKAGE LEAFLET

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

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATION(S)

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 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 "Other precautions" and "Environmental properties".

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).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 administration of a correct dose, body weight should be determined as accurately as possible.

9. ADVICE ON CORRECT ADMINISTRATION

10. 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.

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 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 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 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.

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

Overdose (symptoms, emergency procedures, antidotes)
A threefold overdose is well tolerated without adverse clinical signs.

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

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 "Contraindications" and "Other precautions".

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

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.

Approved 29 September 2022