PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs.
Toltrazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
1 ml contains: Toltrazuril 50.0 mg

Excipients:
Sodium benzoate (E211) 2.1 mg
Sodium propionate (E281) 2.1 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml, 250 ml.

5. TARGET SPECIES

Pigs (piglets), Calves (on dairy farms – see package leaflet “Indications”) and Sheep (lambs).

6. INDICATION(S)

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

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Shake well before use.

DOSAGE:

Piglets & Lambs: Single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.

Calves: Single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.

8. WITHDRAWAL PERIOD

Piglets: Meat and offal: 77 days

Calves: Meat and offal: 63 days
Not permitted for use in lactating animals producing milk for human consumption.

Lambs: Meat and offal: 42 days
Not permitted for use in lactating sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

- 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 animals in a pen.
- Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
- To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
- 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 untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land. Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

USER SAFETY WARNINGS

- Wash any splashes from skin or eyes immediately with water.

10. EXPIRY DATE

Expiry**:** {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.
Shelf life after first opening the container: 3 months.

12. SPECIFIC 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

[Distribution category]

POM-V

For animal treatment only - to be supplied only on veterinary prescription.
A veterinary medicinal product authorised in the UK.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4113

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs.
Toltrazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance: Toltrazuril 50 mg

Excipients: Sodium benzoate (E211) 2.1 mg. Sodium propionate (E281) 2.1 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml, 250 ml.

5. TARGET SPECIES

Pigs (piglets), Calves (on dairy farms – see package leaflet “Indications”) and Sheep (lambs)

6. INDICATION(S)

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

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Shake well before use.

DOSAGE:

Piglets & Lambs: Single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.

Calves: Single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 ml oral suspension per 10 kg body weight.

8. WITHDRAWAL PERIOD

Piglets: Meat and offal: 77 days

Calves: Meat and offal: 63 days
Not permitted for use in lactating animals producing milk for human consumption.

Lambs: Meat and offal: 42 days
Not permitted for use in lactating sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

- 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 animals in a pen.
- Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
- To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
- 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 untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land. Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

USER SAFETY WARNINGS

- Wash any splashes from skin or eyes immediately with water.

10. EXPIRY DATE

Expiry **:** {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.
Shelf life after first opening the container: 3 months.
Date for discarding product after first opening …….

12. SPECIFIC 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

[Distribution category]

POM-V

For animal treatment only – to be supplied only on veterinary prescription.
A veterinary medicinal product authorised in the UK.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4113

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: BAYCOX 50 mg/ml ORAL SUSPENSION FOR PIGLETS, CALVES AND LAMBS

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

Marketing authorisation holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer for batch release:
KVP Pharma + Veterär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs
Toltrazuril

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

1 ml contains:

Active substance:	Toltrazuril	50 mg
Excipients:	Sodium benzoate (E211)	2.1 mg
	Sodium propionate (E281)	2.1 mg

4. INDICATION(S)

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

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

5. CONTRAINDICATIONS

Calves: For environmental reasons: Do not use in calves weighing more than 80 kg body weight. Do not use in fattening units such as veal or beef calves
For more details see “Special Warnings”.

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (piglets), Calves (weighing less than 80 kg on dairy farms – refer to contraindications) and Sheep (lambs).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs i.e. in the prepatent period.
Shake well before use.

Piglets: Each pig 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.
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 animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 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.

Lambs: Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight. If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or over-dosing.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Piglets: Meat and offal: 77 days

Calves: Meat and offal: 63 days
Not permitted for use in lactating animals producing milk for human consumption.

Lambs: Meat and offal: 42 days
Not permitted for use in lactating sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label.
Shelf life after first opening the container: 3 months
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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

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 untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land (see Contraindications).

Lambs kept throughout the whole life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

USER SAFETY WARNINGS
Wash any splashes from skin and eyes immediately with water.

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

October 2020

15. OTHER INFORMATION

100 ml bottle, 250 ml bottle, 1,000 ml bottle.
Not all pack sizes may be marketed.
For animal treatment only – to be supplied only on veterinary prescription.

POM-V

UK authorised veterinary medicinal product
Vm 00879/4113

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. LABEL: 1000 ml CONTAINER

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

Marketing authorisation holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer for batch release:
KVP Pharma + Veterär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 50 mg/ml Oral Suspension for Piglets, Calves and Lambs
Toltrazuril

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

1 ml contains:

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

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

1000 ml

6. INDICATION(S)

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

For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in lambs on farms with a confirmed history of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

7. CONTRAINDICATIONS

Calves: For environmental reasons: Do not use in calves weighing more than 80 kg body weight. Do not use in fattening units such as veal or beef calves
For more details see “Special Warnings”.

8. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

9. TARGET SPECIES

Pigs (piglets), Calves (weighing less than 80 kg on dairy farms – refer to Contraindications) and Sheep (lambs).

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs i.e. in the prepatent period. Shake well before use.

Piglets:
- Each pig 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.
- 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 animal should be treated with a single oral dose of 15 mg toltrazuril/kg body weight corresponding to 3.0 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.

Lambs:
- Each animal should be treated with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
- If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or over-dosing.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Piglets: Meat and offal: 77 days

Calves: Meat and offal: 63 days
Not permitted for use in lactating animals producing milk for human consumption.

Lambs: Meat and offal: 42 days
Not permitted for use in lactating sheep producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

- This veterinary medicinal product does not require any special storage conditions.
- Do not use after the expiry date stated on the label.
- Shelf life after first opening the container: 3 months.
- When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Date for discarding product remaining after first opening _____

14. SPECIAL WARNING(S)

- 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 animals in a pen.
- Hygienic measures may reduce the risk of coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.
- To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
- To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
- 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 untreated cows. Manure from treated calves must be diluted with at least 3 times the weight of manure from mature cows before it can be spread onto land (see Contraindications). Lambs kept throughout the whole

life span indoors under an intensive rearing system must not be treated beyond the age of 6 weeks or body weight of more than 20 kg at treatment. Manure from these animals should only be applied to the same piece of land every third year.

USER SAFETY WARNINGS

- Wash any splashes from skin and eyes immediately with water.

15. EXPIRY DATE

Expiry: {month/year}

16. 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.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

October 2020

18. 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.

POM-V

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4113

21. MANUFACTURER'S BATCH NUMBER

Batch: {number}

22. OTHER INFORMATION

100 ml bottle, 250 ml bottle, 1000 ml bottle.
Not all pack sizes may be marketed.

A veterinary medicinal product authorised in the UK.

Approved 23 October 2020