ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

100 ml or 250 ml Plastic Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Multi 50 mg/ml oral suspension for Cattle, Pigs and Sheep

Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg toltrazuril

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle (calves: dairy calves, beef suckler, bull beef), Pigs (Piglets, 3 - 5 days old), Sheep (lambs).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods

Cattle:
Meat and offal: 63 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 77 days

Sheep:
Meat and offal: 42 days
Milk: Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened, use by _____
Shelf life after first opening the container: 6 months

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4114

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

COMBINED LABEL-LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1000 ml Plastic Bottle

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 responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Straße 324, 24106 Kiel
Germany

2. Name of the veterinary medicinal product

Baycox Multi 50 mg/ml oral suspension for Cattle, Pigs and Sheep

Toltrazuril

3. Statement of the active substance (s) and other ingredients

White or yellowish suspension

Each ml contains:

Active substance:

Toltrazuril	50.0 mg

Excipients:

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

4. Pharmaceutical form

Oral suspension

5. Package size

1000 ml

6. Indication(s)

Cattle: For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in calves on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

Pigs: For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

Sheep: 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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For further information on use in cattle please refer to the table in section 14 Special Warnings, Other precautions.

8. 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.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Cattle (calves: dairy calves, beef suckler, bull beef), Pigs (Piglets, 3 - 5 days old), Sheep (lambs).

10. Dosage for each species, route(s) and method of administration

For oral use.

All Species
The ready-to-use oral suspension must be shaken for 20 seconds before use.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Cattle
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.

Pigs
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.

Sheep
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

None

12. Withdrawal period(s)

Cattle:
Meat and offal: 63 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 77 days

Sheep:
Meat and offal: 42 days
Milk: Not authorised for use in animals producing milk for human consumption.

13. Special storage precautions

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

14. Special warning(s)

Special precautions for each target species:

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. Treatment during an outbreak will be of limited value for the individual animal because of damage to the small intestine having already occurred.

As with any antiparasiticide frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

If resistance is present it should be considered to use another antiprotozoal from another class and with a different mechanism of action.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medical product.
Avoid skin and eye contact with the product.
In case of accidental exposure to the skin or eyes, wash immediately with water.
Do not eat, drink or smoke while using the product.

Other precautions:

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both very persistent (half-life ca. 1 year) and mobile in soil and to be toxic to plants including crop species.

For the mentioned environmental reasons the following restrictions on the use apply:

Cattle:

Veal calves	Not to be used in veal calves.
Dairy calves	Do not administer to dairy calves weighing more than 80 kg bodyweight 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.
Suckler calves	Do not administer to suckler calves weighing more than 150 kg

	bodyweight.
Bull beef calves	Not to be used to treat bull beef calves less than 3 months old. Do not administer to bull beef calves weighing more than 150 kg bodyweight.

Sheep: 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.

Pigs: None.

Pregnancy and lactation:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
None known.

In pigs there is no interaction in combination with iron supplementation.

Incompatibilities:
In absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicines.

Overdose (symptoms, emergency procedures, antidotes):

No signs of intolerance have been observed in healthy piglets and calves with a threefold overdose.
No signs of overdose have been observed in lamb safety studies with threefold overdose at a single treatment and twofold overdose treatment on 2 consecutive days.

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

September 2021

17. Other information

Pack sizes: 100, 250 and 1000 ml bottles
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}
Once opened, use by _____
Shelf life after first opening the container: 6 months
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.

21. Marketing authorisation number(s)

Vm 00879/4114

22. Manufacturer’s batch number

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Baycox Multi 50 mg/ml oral suspension for Cattle, Pigs and Sheep

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 responsible for the batch release:
KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Multi 50 mg/ml oral suspension for Cattle, Pigs and Sheep

Toltrazuril

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

White or yellowish suspension

Each ml contains:

Active substance:

Toltrazuril	50.0 mg

Excipients:

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

4. INDICATION(S)

Cattle: For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in calves on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

Pigs: For the prevention of clinical signs of coccidiosis in neonatal piglets (3-5 days old) on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

Sheep: 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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. For further information on use in cattle please refer to the table in section 12 Special Warnings, Other precautions.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (calves: dairy calves, beef suckler, bull beef), Pigs (Piglets, 3 - 5 days old), Sheep (lambs).

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

For oral use.

All Species
The ready-to-use oral suspension must be shaken for 20 seconds before use.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Cattle
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.

Pigs
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.

Sheep
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

None

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 63 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 77 days

Sheep:
Meat and offal: 42 days
Milk: 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 which is stated on the label after EXP.
The expiry date refers to the last day of that month.

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

Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Special precautions for each target species:

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.

Treatment during an outbreak will be of limited value for the individual animal because of damage to the small intestine having already occurred.

As with any antiparasiticide frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

If resistance is present it should be considered to use another antiprotozoal from another class and with a different mechanism of action.

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medical product.
Avoid skin and eye contact with the product.
In case of accidental exposure to the skin or eyes, wash immediately with water.
Do not eat, drink or smoke while using the product.

Other precautions:

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both very persistent (half-life ca.1 year) and mobile in soil and to be toxic to plants including crop species.

For the mentioned environmental reasons the following restrictions on the use apply:

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Suckler calves	Do not administer to suckler calves weighing more than 150 kg bodyweight.
Bull beef calves	Not to be used to treat bull beef calves less than 3 months old. Do not administer to bull beef calves weighing more than 150

	kg bodyweight.

Sheep: 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.

Pigs: None.

Pregnancy and lactation:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
None known.

In pigs there is no interaction in combination with iron supplementation.

Incompatibilities:
In absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicines.

Overdose (symptoms, emergency procedures, antidotes):

No signs of intolerance have been observed in healthy piglets and calves with a threefold overdose.
No signs of overdose have been observed in lamb safety studies with threefold overdose at a single treatment and twofold overdose treatment on 2 consecutive days.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

Pack sizes: 100, 250 and 1000 ml bottles
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 01 December 2021