PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer Carton, 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains:

Active substance:
toltrazuril 25 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Colourless to brown solution.

4. PACKAGE SIZE

1 x 100 ml

5. TARGET SPECIES

Chickens (broilers, pullets and breeders) and turkeys

6. INDICATION(S)

Anticoccidial agent.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration via the drinking water.
In order to ensure administration of a correct dose, the total weight of the treated animals and the daily water consumption must be accurately calculated.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Chickens:
Meat and offal: 16 days

Turkeys:
Meat and offal: 16 days

Not for use in birds producing or intended to produce eggs for human consumption.
Do not use within 6 weeks before the start of the laying period.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months.
Once opened use by…
Once diluted use the medicated water within 24 hours, any water not consumed to be discarded.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Vm 00879/4112

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

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

1000 ml bottle, 5000 ml 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- und Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel

2. Name of the veterinary medicinal product

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys

3. Statement of the active substance and other ingredients

1 ml solution contains:

Active substance:
toltrazuril 25 mg

Colourless to brown solution.

4. Pharmaceutical form

Solution for use in drinking water.

5. Package size

1000 ml
5000 ml

6. Indication(s)

For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens: *E. acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. tenella*.
Turkeys: *E. adenoides* and *E. meleagrimitis*.

7. Contraindications

Do not use in animals with hypersensitivity to the active substance or to any of the excipients.

8. Adverse reactions

None known.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Chickens (broilers, pullets and breeders) and turkeys

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

For oral administration via the drinking water.
In order to ensure administration of a correct dose, the total weight of the treated animals and the daily water consumption must be accurately calculated.

The dose is 7 mg toltrazuril per kg body weight (bw) per day (= 0.28 ml [product] per kg bw per day). Treatment is carried out on two consecutive days.
The medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.
In case an automatic dose dispenser is used, the medical product should be administered for one period of 8 hours per day on 2 consecutive days.
Medicated drinking water should be refreshed every 24 hours.
The dosage should be based on the current, actual drinking water intake of the animals, because this varies depending on the animal species, on the age, state of health and intended use of the animals, and depending on the housing conditions (e.g. different ambient temperature, different lighting regime).

In the case of continuous treatment over 24 hours, the volume of the product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of the product required per litre drinking water:

0.28 ml [product] per kg bw per day	x	Average bw (kg) of the animals to be treated	=	x ml [product] per litre drinking water
drinking water intake in litres over 24 hours per animal		Average		

Total volume of the product required per day (24 h):
The calculated volume (x ml [product] per litre) must be multiplied by the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the volume of the product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of the product required per litre drinking water:

0.28 ml [product] per kg bw per day	x	Average bw (kg) of the animals to be treated	=	y ml [product] per litre drinking water
drinking water intake in litres over 8 hours per animal		Average		

Total volume of the product required for a treatment period of 8 hours:
The calculated volume (y ml [product] per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

11. Advice on correct administration

The appropriate volume of solution must be added daily to the drinking water while stirring.

If volumes of between 1 and 4 ml product are added per litre drinking water, solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.
Predilution and the administration through a dosing pump (proportioner) are not recommended. Use preferably a bulk tank.

12. Withdrawal period(s)

Chickens:
Meat and offal: 16 days

Turkeys:
Meat and offal: 16 days

Not for use in birds producing or intended to produce eggs for human consumption.
Do not use within 6 weeks before the start of the laying period.

13. Special storage precautions

Do not store above 25 °C

Shelf life after first opening the container: 3 months

Once opened, use by ...

Do not use this veterinary medicinal product after the expiry date (EXP:) which is stated on the container. The expiry date refers to the last day of that month.

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the product.

Once diluted use medicated water within 24 hours, any water not consumed to be discarded.

14. Special warnings

Special warnings for each target species:
Good hygiene can reduce the risk of coccidiosis. It is therefore recommended any deficiencies in husbandry should be addressed in addition to treatment. Poultry houses should be kept clean and dry.

It is recommended to treat all animals in a pen. For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

Special precautions for use in animals:
As with all anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.

If resistance is present it should be considered to use other antiprotozoal from another class/mechanism of action.

This VMP should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like ‘coccidiostats’ and ‘histomonostats.

For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

The veterinary medicinal product is a strongly alkaline solution and should not be administered undiluted.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Contact with skin and mucous membranes should be avoided.
Wear synthetic rubber gloves when handling the product.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

Lay:
Not applicable, see section 12, Withdrawal periods.

Interaction with other medicinal products and other forms of interaction:
Combination of the product with antibiotics may result in reduced water intake in turkeys. The concomitant administration of other substances to the drinking water should be avoided.
Overdose (symptoms, emergency procedures, antidotes):
A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

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

15. 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.

16. Date on which the label was last approved

June 2023

17. Other information

Nature and composition of immediate packaging
100 ml (available in cartons of 1 x 100 ml) white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.

5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization 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}

21. Marketing authorisation number

Vm 00879/4112

22. Manufacturer’s batch number

Lot {number}

PACKAGE LEAFLET:
Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys

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- und Veterinär Produkte GmbH
Projensdorfer Str. 324
D-24106 Kiel

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 25 mg/ml, solution for use in drinking water for chickens and turkeys

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

1 ml solution contains:

Active substance:
toltrazuril 25 mg

Colourless to brown solution

4. INDICATION(S)

For the treatment of coccidiosis in chickens and turkeys, caused by infections with various species of *Eimeria*:

Chickens: *E. acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. tenella*.
Turkeys: *E. adenoides* and *E. meleagrimitis*.

5. CONTRAINDICATIONS

Do not use in animals with hypersensitivity to the active substance or to any of the excipients.

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

Chickens (broilers, pullets and breeders) and turkeys

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

For oral administration via the drinking water.

In order to ensure administration of a correct dose, the total weight of the treated animals and the daily water consumption must be accurately calculated.
The dose is 7 mg toltrazuril per kg body weight (bw) per day (= 0.28 ml [product] per kg bw per day). Treatment is carried out on two consecutive days.
The medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.
In case an automatic dose dispenser is used the medicinal product should be administered for one period of 8 hours per day for 2 consecutive days.
Medicated drinking water should be refreshed every 24 hours.

The dosage should be based on the current, actual drinking water intake of the animals, because this varies depending on the animal species, on the age, state of health and intended use of the animals, and depending on the housing conditions (e.g. different ambient temperature, different lighting regime).

In the case of continuous treatment over 24 hours, the volume of the product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of the product required per litre drinking water:

$$\frac{\text{0.28 ml [product] per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average drinking water intake in litres over 24 hours per animal}} = \text{x ml [product] per litre drinking water}$$

Total volume of the product required per day (24 h):
The calculated volume (x ml [product] per litre) must be multiplied by the total consumption of drinking water (l) per day (24 h).

In the case of treatment for a period of 8 hours per day, the volume of the product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Volume of the product required per litre drinking water:

$$\frac{\text{0.28 ml [product] per kg bw per day treated} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average drinking water intake in litres over 8 hours per animal}} = \text{y ml [product] per litre drinking water}$$

Total volume of the product required for a treatment period of 8 hours: The calculated volume (y ml [product] per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

9. ADVICE ON CORRECT ADMINISTRATION

The appropriate volume of solution must be added daily to the drinking water while stirring.

If volumes of between 1 and 4 ml product are added per litre drinking water, solubility is guaranteed over the period of treatment.

In order to ensure that all the animals drink water evenly, sufficient space must be made available at the waterer. Free-range animals must be kept indoors during treatment.

After the end of the treatment, the watering system must be cleaned in an appropriate manner in order to prevent any exposure to residual subtherapeutic doses, particularly if liable to promote the development of resistance.
Predilution and the administration through a dosing pump (proportioner) are not recommended. Use preferably a bulk tank.

10. WITHDRAWAL PERIOD(S)

Chickens:
Meat and offal: 16 days

Turkeys:
Meat and offal: 16 days

Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 6 weeks before the start of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C

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.

Do not use this veterinary medicinal product after the expiry date (EXP:) which is stated on the container. The expiry date refers to the last day of that month.

After a prolonged storage period, yellow to yellow-brown discoloration of the solution may occur, although this does not impair the quality of the product.

Once diluted use medicated water within 24 hours, any water not consumed to be discarded.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Good hygiene can reduce the risk of coccidiosis. It is therefore recommended any deficiencies in husbandry should be addressed in addition to treatment. Poultry houses should be kept clean and dry.

It is recommended to treat all animals in a pen. For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

Special precautions for use in animals:
As with any anticoccidials, frequent and prolonged use of an antiprotozoal of the same class may result in the development of resistances. It is important to keep to the recommended dose in order to minimise the risk of resistance.

If resistance is present it should be considered to use another antiprotozoal from another class/mechanism of action.

This VMP should not be used together with feed additives/or other veterinary medicinal products that might interfere with the efficacy of the product, like "coccidiostats" and "histomonostats".

For best results, treatment should be initiated before the clinical signs of disease have spread throughout the whole group.

The veterinary medicinal product is a strongly alkaline solution and should not be

administered undiluted.

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

People with known hypersensitivity to toltrazuril should avoid contact with the veterinary medicinal product.
The veterinary medicinal product is an alkaline solution.
Contact with skin and mucous membranes should be avoided. Wear synthetic rubber gloves when handling the product.
In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke during use.
Wash hands after use.

Lay:
Not applicable, see section 10, Withdrawal periods.

Interaction with other medicinal products and other forms of interaction:
Combination of the product with antibiotics may result in reduced water intake in turkeys. The concomitant administration of other substances to the drinking water should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
A reduction in drinking water intake may be the first sign of an overdose. This is observed only after an overdose with more than 10 times the recommended dose.

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

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

June 2023

15. OTHER INFORMATION

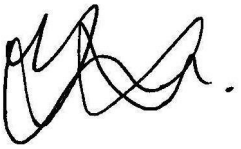
Nature and composition of immediate packaging
100 ml (available in cartons of 1 x 100 ml) white HDPE bottles closed with light

green polypropylene screw cap with a red tamper evident seal.
1000 ml white HDPE bottles closed with light green polypropylene screw cap with a red tamper evident seal.
5000 ml white HDPE canister with an aluminium sealing disc, closed with a black polyethylene screw cap and a yellow tamper evident seal.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

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



Approved: 27 June 2023