

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box, 100 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

**Active substance:**

Toltrazuril 25 mg/ml

**3. PACKAGE SIZE**

100 ml

**4. TARGET SPECIES**

Chickens (broilers, pullets and breeders) and turkeys

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

In drinking water use.

**7. WITHDRAWAL PERIODS**

**Withdrawal periods:**

Meat and offal:

Chickens: 16 days

Turkeys: 16 days

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

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the container: 3 months.

Once opened use by...

Once diluted use within 24 hours

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C

**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**

Elanco GmbH

**14. MARKETING AUTHORISATION NUMBERS**

UK(GB) Vm 52127/5154

UK(NI) Vm 52127/3079

**15. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL 100 ml bottle**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

### **2. STATEMENT OF ACTIVE SUBSTANCES**

#### **Active substance:**

Toltrazuril 25 mg/ml

### **3. TARGET SPECIES**

Chickens (broilers, pullets and breeders) and turkeys

### **4. ROUTES OF ADMINISTRATION**

In drinking water use.

Read the package leaflet before use.

### **5. WITHDRAWAL PERIODS**

Withdrawal periods:

Meat and offal:

Chickens: 16 days

Turkeys: 16 days

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

### **6. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the container: 3 months.

Once opened use by...

Once diluted use within 24 hours

### **7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C

### **8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Elanco GmbH

**9. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Baycox 25 mg/ml, Solution for Use in Drinking Water for Chickens and Turkeys

#### **2. Composition**

Each ml solution contains

##### **Active substance:**

Toltrazuril 25 mg

Colourless to brown solution,

#### **3. Target species**

Chickens (broilers, pullets and breeders) and turkeys

#### **4. Indications for use**

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 cases of hypersensitivity to the active substance or to any of the excipients

#### **6. Special warnings**

##### Special warnings:

Good hygiene can reduce the risk of coccidiosis. It is therefore recommended that 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 safe use in the target species:

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 veterinary medicinal product 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".

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.

Personal protective equipment consisting of synthetic rubber gloves should be worn when handling the veterinary medicinal product.

Contact with skin, mucous membranes and ingestion should be avoided.

In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.

In case of accidental spillage onto skin or 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.

Laying birds:

Not applicable, see section "Withdrawal periods".

Interactions with other medicinal products and other forms of interaction:

Combination of the veterinary medicinal 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:

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

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

## **7. Adverse events**

Chickens (broilers, pullets and breeders) and turkeys: None known

Reporting adverse events is important. It allows continuous safety monitoring of a 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## **8. Dosage for each species, routes and method of administration**

In drinking water use. For oral administration.

To ensure a correct dosage, body weight (bw) of the treated animals and the daily water consumption should be determined as accurately as possible.

The recommended dose rate is 7 mg toltrazuril per kg (bw) per day (equivalent to 0.28 ml veterinary medicinal product per kg bw per day). Treatment is carried out on two consecutive days.

The veterinary medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.

In case an automatic dose dispenser is used the veterinary 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 intake of medicated water depends on the clinical condition of the animals, such as the animal species, the age, state of health and intended use of the animals, and the housing conditions (e.g. different ambient temperature, different lighting regime). In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

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

**Volume of veterinary medicinal product required per litre of drinking water:**

$\frac{0.28 \text{ ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average daily water intake (litres per animal)}} = \text{x ml veterinary medicinal product per litre of drinking water}$
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**Total volume of veterinary medicinal product required per day (24 h):**

The calculated volume (x ml veterinary medicinal product per litre) must be multiplied with 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 required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:**

**Volume of veterinary medicinal product required per litre of drinking water:**

$\frac{0.28 \text{ ml veterinary medicinal product per kg bw per day} \times \text{Average bw (kg) of the animals to be treated}}{\text{Average 8 hours water intake (litres per animal)}}$	=	$y \text{ ml veterinary medicinal product per litre of drinking water}$
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**Total volume of veterinary medicinal product required for a treatment period of 8 hours:**

The calculated volume (y ml veterinary medicinal 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 the veterinary medicinal product must be added daily to the drinking water while stirring.

At doses ranging from 1 and 4 ml of the veterinary medicinal product per litre of drinking water, the 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. Preferably use a bulk tank.

**10. Withdrawal periods**

Chickens:

Meat and offal: 16 days

Turkeys:

Meat and offal: 16 days

Not authorised for use in birds producing 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 immediate packaging: 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 which is stated on the container after Exp. 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 veterinary medicinal product.

Once opened, use by ...

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

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

UK(GB) Vm 52127/5154

UK(NI) Vm 52127/3079

### Pack sizes:

100 ml or 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

#### **15. 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](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse events:

Elanco GmbH  
Heinz-Lohmann Strasse 4  
Groden  
27472 Cuxhaven  
Germany  
[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)  
[PV.XXI@elancoah.com](mailto:PV.XXI@elancoah.com)  
Tel: +44 3308221732

Manufacturer responsible for batch release:

KVP Pharma und Veterinär Produkte GmbH  
Projensdorfer Str. 324  
24106 Kiel Germany

#### **17. Other information**

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**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET - Combined label and package leaflet 1000ml and 5000 ml bottle**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Baycox 25 mg/ml, Solution for Use in Drinking Water for Chickens and Turkeys

**2. COMPOSITION**

**Active substance:**

Toltrazuril 25 mg/ml

Colourless to brown solution.

**3. PACKAGE SIZE**

1000 ml

5000 ml

**4. TARGET SPECIES**

Chickens (broilers, pullets and breeders) and turkeys

**5. INDICATIONS FOR USE**

**Indications for use**

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*.

**6. CONTRAINDICATIONS**

**Contraindications**

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

## 7. SPECIAL WARNINGS

### Special warnings

Good hygiene can reduce the risk of coccidiosis. It is therefore recommended that 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 safe use in the target species:

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 veterinary medicinal product 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'.

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.

Personal protective equipment consisting of synthetic rubber gloves should be worn when handling the veterinary medicinal product.

Contact with skin, mucous membranes and ingestion should be avoided.

In case of direct contact with the eyes or skin, wash immediately and thoroughly with water.

In case of accidental spillage onto skin or 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.

#### Laying birds:

Not applicable, see section "Withdrawal periods".

#### Interaction with other medicinal products and other forms of interaction:

Combination of the veterinary medicinal 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:

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.

Special restrictions for use and special conditions for use:  
Not applicable.

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**

Chickens (broilers, pullets and breeders) and turkeys: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this label, 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 on this label, or via your national reporting system at: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto: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**

In drinking water use. For oral administration.

To ensure a correct dosage, body weight (bw) of the treated animals and the daily water consumption should be determined as accurately as possible.

The recommended dose rate is 7 mg toltrazuril per kg bw per day (equivalent to 0.28 ml of veterinary medicinal product per kg bw per day). Treatment is carried out on two consecutive days.

The veterinary medicinal product should be administered continuously over 24 hours per day for 2 consecutive days.

In case an automatic dose dispenser is used the veterinary 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 intake of medicated water depends on the clinical condition of the animals, such as the animal species, the age, state of health and intended use of the animals and the housing conditions (e.g. different ambient temperature, different lighting regime). In order to obtain the correct dosage, the concentration of toltrazuril may need to be adjusted accordingly.

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

**Volume of veterinary medicinal product required per litre of drinking water:**

0.28 ml veterinary medicinal product per kg bw per day	$\times$	Average bw (kg) of the animals to be treated	=	x ml veterinary medicinal product per litre of drinking water
Average daily water intake (litres per animal)				

**Total volume of veterinary medicinal product required per day (24 h):**

The calculated volume (x ml veterinary medicinal product per litre) must be multiplied with 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 required amount of veterinary medicinal product to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:**

**Volume of veterinary medicinal product required per litre of drinking water:**

0.28 ml veterinary medicinal product per kg bw per day	$\times$	Average bw (kg) of the animals to be treated	=	y ml veterinary medicinal product per litre of drinking water
Average 8 hours water intake (litres per animal)				

**Total volume of veterinary medicinal product required for a treatment period of 8 hours:**

The calculated volume (y ml veterinary medicinal product per litre) must be multiplied by the total consumption of drinking water (l) per 8-hour period.

## **10. ADVICE ON CORRECT ADMINISTRATION**

### **Advice on correct administration**

The appropriate volume of the veterinary medicinal product must be added daily to the drinking water while stirring.

At doses ranging from 1 and 4 ml of the veterinary medicinal product per litre of drinking water, the 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. Preferably use a bulk tank.

## **11. WITHDRAWAL PERIODS**

### **Withdrawal periods**

Chickens:

Meat and offal: 16 days

Turkeys:

Meat and offal: 16 days

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

## **12. SPECIAL STORAGE PRECAUTIONS**

### **Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the container after Exp. 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.

## **13. SPECIAL PRECAUTIONS FOR DISPOSAL**

### **Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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**

### **Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(GB) Vm 52127/5154

UK(NI) Vm 52127/3079

### Pack sizes

100 ml and 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.

## 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](http://www.gov.uk).

## 17. CONTACT DETAILS

### Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Elanco GmbH  
Heinz-Lohmann Strasse 4  
Groden  
27472 Cuxhaven  
Germany  
[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)  
[PV.XXI@elancoah.com](mailto:PV.XXI@elancoah.com)  
Tel: +44 3308221732

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324  
24106 Kiel  
Germany

## 18. OTHER INFORMATION

### Other information

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## 19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}

Once diluted use within 24 hours.

Once opened, use by ...

Shelf life after first opening the immediate packaging: 3 months

## 21. BATCH NUMBER

Lot {number}

*Gavin Hall*  
Approved: 17 April 2026