SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml solution contains:

Active substance:
Toltrazuril 25 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 200
Trolamine

Colourless to brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, pullets and breeders) and turkeys

3.2 Indications for use for each target species

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*.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable (see section 3.12).

3.8 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.

3.9 Administration routes and dosage

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	x	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	x	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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51BC01

4.2 Pharmacodynamics

Toltrazuril is an anticoccidial of the triazinetrione group, active against *Eimeria* spp. Toltrazuril induces changes in the fine structure of the developmental stages of coccidia. These are caused primarily by swelling of the endoplasmic reticulum and of the Golgi apparatus, abnormal changes to the perinuclear space and disturbances in cell division. Toltrazuril causes a decrease in the activity of respiratory chain enzymes in the parasites.

4.3 Pharmacokinetics

After oral administration, toltrazuril undergoes at least 50% absorption in poultry. The highest concentrations are to be found in the liver and kidneys of the poultry. The active substance is broken down rapidly. The main metabolite is toltrazuril sulfone.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life after first opening the immediate packaging: 3 months

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.

Shelf life after dilution or reconstitution according to directions: 24 hours

5.3 Special precautions for storage

Do not store above 25 C.

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBERS

UK(GB) Vm 52127/5154
UK(NI) Vm 52127/3079

8. DATE OF FIRST AUTHORISATION

29 July 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 11 November 2025