SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Toltrazuril 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Docusate sodium	
Simethicone emulsion	
Bentonite	
Citric acid (for pH adjustment)	
Xanthan gum	
Propylene glycol	
Water, purified	

White or yellowish suspension.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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.

3.3 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 3.5 Special precautions for use, Special precautions for the protection of the environment.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 medicinal product.
Avoid skin and eye contact with the product.
In case of accidental exposure to the eyes or spillage onto skin, wash immediately with water.
Do not eat, drink or smoke while using the product.

Special precautions for the protection of the environment:

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 body weight.

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

3.6 Adverse events

Cattle, Pigs and Sheep: 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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

In pigs there is no interaction in combination with iron supplementation

3.9 Administration routes and dosage

For oral use.

All Species
The ready-to-use oral suspension must be shaken for 20 seconds before use.
To ensure a correct dosage, 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.

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

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

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51BC01

4.2 Pharmacodynamics

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus Cystoisospora and Eimeria. It is active against all intracellular development stages of coccidia of the merogony (asexual multiplication) and gamogony (sexual phase). All stages are destroyed, thus the mode of action is coccidiocidal.

4.3 Pharmacokinetics

Cattle:
After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (Cmax = 36.6 mg/l) was observed between 24 and 48 hours (geometric mean 33.9 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (64.2 hours). The main

metabolite is characterised as toltrazuril sulfone. The major route of excretion is via the faeces.

Pigs:
After oral administration toltrazuril is slowly absorbed with a bioavailability of 70%. The main metabolite is characterised as toltrazuril sulfone. The elimination of toltrazuril is slow with a half-life elimination time around 3 days. The major route of excretion is via the faeces.

Sheep:
After oral administration toltrazuril is slowly absorbed in mammals. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration (Cmax = 62 mg/L) was observed 2 days following oral administration. The elimination of toltrazuril is slow with an elimination half-life time of approximately 9 days. The major route of excretion is via the faeces.

Environmental properties

Cattle and Sheep
The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a very persistent (half-life ca. 1 year) and mobile compound and has adverse effects on both the growth and emergence of plants. Given the persistent properties of ponazuril repeated spreading of manure from treated animals may lead to an accumulation in the soil and consequently a risk to plants. The accumulation of ponazuril in soil together with its mobility also leads to a risk of leaching to groundwater. See sections 3.3 and 3.5.

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: 6 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100, 250 and 1000 ml high density polyethylene bottles closed with polypropylene screw caps.

One 100 ml or 250 ml bottle is packed in a cardboard box.
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 Europe Ltd

7. MARKETING AUTHORISATION NUMBERS

Vm 00879/5055
Vm 00879/3040

8. DATE OF FIRST AUTHORISATION

06 October 2016

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

June 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: 19 September 2025