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

1 ml contains:
Active subtsance:
Toltrazuril 50 mg

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
White or yellowish suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the 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*.

4.3 Contraindications

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

4.4 Special warnings 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.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known sensitivity to the active substance or any of the excipients should avoid contact with this product.
Avoid skin and eye contact with the product.
Wash any splashes form skin or eyes 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.

For environmental reasons:

Cattle: Not to be used in veal calves.
Do not administer to dairy calves weighing more than 80 kg bodyweight or to bull beef or suckler calves weighting more than 150 kg bodyweight.
Not to be used to treat bull beef calves less than 3 months old.
For dairy calves: 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.

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration.

All Species

The ready-to-use oral suspension must be shaken for 20 seconds before use.
To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A threefold overdose is well tolerated by healthy piglets and calves without signs of intolerance.
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.

4.11 Withdrawal period(s)

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

Pigs:
Meat and offal: 77 days

Sheep:
Meat and offal: 42 days
Not permitted for use in lactating sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, triazines, ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Isospora* and *Eimeria*. It isactive 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 coccidoicidal.

5.2 Pharmacokinetic particulars

Cattle:
After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration (C_{max} = 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 (C_{max} = 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 4.3 and 4.5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Docusate sodium
Simethicone emulsion
Bentonite
Citric acid, anhydrous (for pH adjustment)
Xanthan gum
Propylene glycol
Water, purified

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

100, 250 and 1000 ml high density polyethylene bottles closed with polypropylene screw caps.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10021/073/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 November 2016

10 DATE OF REVISION OF THE TEXT

January 2018