Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox Sheep, 50 mg/ml oral suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 ml contains:

Toltrazuril	50.0 mg

Excipients:

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

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White or yellowish oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

For Sheep (lambs).

4.2 Indications for use, specifying the target species

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

None.

4.4 Special warnings for each target species

As with any antiparasiticide frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.
It is recommended to treat all lambs in a pen.
Hygienic measures may reduce the risk of ovine 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.

4.5 Special precautions for use

Special precaution for use in animal
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash any splashes from skin or eyes immediately with water.

For environmental reasons:

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.

The major metabolite of toltrazuril, toltrazuril sulfone (ponazuril), has been shown to be both persistent (half-life >1 year) and mobile in soil and to be toxic to plants.

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

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. To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, *i.e.* in the prepatent period..
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.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

0.4 ml oral suspension per kg body weight.

The ready-to-use oral suspension must be shaken before use.

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

No signs of overdose have been observed in target animal safety studies with threefold overdose at a single treatment and twofold overdose at treatment on two consecutive days.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals,
ATCvet code: QP 51 AJ 01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus *Eimeria*. It isacting 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.

5.2 Pharmacokinetic particulars

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
The metabolite of toltrazuril, toltrazuril sulfone (ponazuril) is a persistent (half-life >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 also section 4.5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Propionate (E281)
Sodium Benzoate (E211)
Docusate Sodium
Simethicone Emulsion
Bentonite
Citric Acid Anhydrous
Xanthan Gum
Propylene Glycol
Water , Purified

6.2 Major incompatibilities

None known.

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: 3 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

High density polyethylene bottles containing 100, 250 or 1000 ml of a white or yellowish suspension with a blue polypropylene screw cap for the 100 ml bottle and a green polypropylene screw cap for the 250 ml and 1000 ml bottle.

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 material materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 January 2009
Date of last renewal: 07 September 2012

10 DATE OF REVISION OF THE TEXT

October 2020