

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Baycox 50 mg/ml oral suspension for Piglets, Calves and Lambs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 ml contains:

#### **Active substance:**

Toltrazuril 50 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**

Oral suspension  
White or yellowish suspension

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Pig (piglets), Calves (on dairy farms – see section 4.3) and Sheep (lambs)

#### **4.2 Indications for use, specifying the target species**

Piglets: For the prevention of clinical signs of coccidiosis in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Isospora suis*.

Calves: For the prevention of clinical signs of coccidiosis and reduction of coccidia shedding in housed calves replacing cows producing milk for human consumption (dairy cows) on farms with a confirmed history of coccidiosis caused by *Eimeria bovis* or *Eimeria zuernii*.

Lambs: 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**

For environmental reasons:

Do not use in calves weighing more than 80 kg bodyweight.

Do not use in fattening units such as veal or beef calves

For more details see sections 4.5, other precautions and section 5.3, environmental properties.

### **4.4 Special warnings**

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 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.

### **4.5 Special precautions for use**

#### **i. Special precautions for use in animals**

#### **ii. 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.

#### **iii. Other Precautions**

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.

For environmental reasons:

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.

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.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known

#### **4.7 Use during pregnancy, lactation or lay**

Laboratory studies in rat and rabbit have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.9 Amounts to be administered and administration route**

##### **All Species**

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

##### **Piglets**

Individual animal treatment.

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.

Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

##### **Calves**

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.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

##### **Lambs**

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.

#### **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)**

##### **Piglets**

Meat and offal: 77 days

##### **Calves**

Meat and offal: 63 days

Not permitted for use in lactating animals producing milk for human consumption.

##### **Lambs**

Meat and offal: 42 days

Not permitted for use in lactating sheep producing milk for human consumption.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiprotozo-products, ATCvet code: QP51AJ01

### **5.1 Pharmacodynamic properties**

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

#### **Piglets**

After oral administration toltrazuril is slowly absorbed with a bioavailability of  $\geq 70\%$ . 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.

### **Calves**

After oral administration in cattle toltrazuril is slowly absorbed. The maximal plasma concentration ( $C_{max} = 36.6 \text{ mg/l}$ ) 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.

### **Lambs**

After oral administration toltrazuril is slowly absorbed in mammals. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration ( $C_{max} = 62 \text{ mg/L}$ ) 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

## **5.3 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 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  
Xanthan gum  
Propylene glycol  
Purified water,

### **6.2 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 container: 3 months.

#### **6.4 Special precautions for storage**

No special precautions for storage

#### **6.5 Nature and composition of immediate packaging**

High density polyethylene bottles containing 100, 250, 1,000 ml of a white or yellowish suspension with a blue polypropylene screw cap for the 100 ml bottle, and a green one for the 250 ml bottle and 1000 ml bottle.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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 requirements.

### **7. MARKETING AUTHORISATION HOLDER**

Elanco Europe Ltd.  
Form 2, Bartley Way  
Bartley Wood Business Park  
Hook  
RG27 9XA  
United Kingdom

### **8. MARKETING AUTHORISATION NUMBER**

Vm 00879/4113

### **9. DATE OF FIRST AUTHORISATION**

20 August 2009

### **10. DATE OF REVISION OF THE TEXT**

October 2020

Revised: October 2020  
AN: 00937/2020

Approved 23 October 2020

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.