Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baycox 50 mg/ml oral suspension, pig

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 ml contains:
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

Pigs (Piglet 3 - 5 days old).

4.2 Indications for use, specifying the target species

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 *Isospora suis*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None known.

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.

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, e.g there is no interaction in combination with iron supplementation.

4.9 Amounts to be administered and administration route

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.

The oral suspension must be shaken before use.

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

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

No signs of intolerance were observed in piglets up to threefold overdose.

4.11 Withdrawal period(s)

Meat and offal: 77 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoal productATC vet code: QP 51 AJ 01

5.1 Pharmacodynamic properties

Toltrazuril is a triazinon derivative. It acts against coccidia of the genus Isospora. 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

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Sodium docusate
Simethicone emulsion
Bentonite
Citric acid, anhydrous
Xanthan gum
Propylene glycol

Purified water

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening of the container: 6 months
Discard unused material

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,
the 100 and 250 ml bottles are provided in card boxes.

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 should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/059/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 November 2002
Date of last renewal: 10 October 2007

10 DATE OF REVISION OF THE TEXT

October 2020