Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovicox 50 mg/ml oral suspension for cattle and sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of oral suspension contains:

Active substance:

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.
Thick white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (calves on dairy farms).
Sheep (lambs).

4.2 Indications for use, specifying the target species

Cattle:
For the prevention of clinical signs of coccidiosis and reduction of oocyst 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*.

Sheep:
For the prevention of clinical signs of coccidiosis and reduction of oocyst 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 hypersensitivity to the active substance or to any of the excipients.

Cattle:
For environmental reasons:
Do not use in calves weighing more than 80 kg body weight.
Do not use in fattening units such as veal or beef calves.
For more details see sections 4.5, other precautions and section 5, environmental properties.

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 calves or lambs 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

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 hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.
Wash any splashes from skin or eyes immediately with water.

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.
In order to prevent any adverse effects on plants and possible contamination of groundwater, manure from treated calves must be 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

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 use.

Cattle:
Each animal: a single oral dose of 15 mg toltrazuril/kg body weight (i.e. 3.0 ml of the product/10 kg bw.).
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.

Sheep:
Each animal: a single oral dose of 20 mg toltrazuril/kg body weight (i.e. 0.4 ml of the product/kg bw.).
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.

The ready-to-use oral suspension must be shaken before use.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.
Treatment during an outbreak will be of limited value for the individual animal, because of damage to the small intestine having already occurred.

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

A threefold overdose is well tolerated by calves without signs of intolerance. In lambs, no signs of overdose have been observed with threefold overdose at a single treatment and twofold overdose at treatment on two consecutive days.

4.11 Withdrawal period(s)

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

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, triazines, toltrazuril.
ATCvet code: QP51AJ01

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

Cattle:
After oral administration of the product in cattle, toltrazuril is slowly absorbed. The maximal plasma concentration (Cmax = 41.4 mg/l) was observed between 6.00 and 48 hours (median 18 hours) following oral administration. The elimination of toltrazuril is slow with a terminal half-life time of approximately 2.5 days (59.5 hours). The main metabolite is characterised as toltrazuril sulfone. The major route of excretion is *via* the faeces.

Sheep:
After oral administration of the product in sheep, toltrazuril is slowly absorbed. The main metabolite is characterised as toltrazuril sulfone. The maximal plasma concentration (C_{max} = 64.6 mg/L) was observed between 12 and 120 hours (median 18 hours) following a single oral dose of 20 mg/kg bw.
The elimination of toltrazuril is slow with an elimination half-life time of up to 9 days (mean 5 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 sections 4.3 and 4.5.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sodium propionate (E281)
Propylene glycol
Docusate sodium
Simeticone emulsion
Aluminium magnesium silicate
Citric acid monohydrate

Xanthan gum
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: 3 years.
Shelf-life after first opening the immediate packaging: 1 year.

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

Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 250 ml of oral suspension in a box.
Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 1000 ml of oral suspension in a box.

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 requirements.

7 MARKETING AUTHORISATION HOLDER

J. & M. Veterinary Services Ltd
30 Coolmine Business Park,
Clonsilla Road,
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10954/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th September 2013
Date of last renewal: 19th September 2018

10 DATE OF REVISION OF THE TEXT

September 2019