1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovicox 50 mg/ml oral suspension for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of oral suspension contains:

Active substance:
Toltrazuril 50 mg

Excipients:

Qualitative composition of excipients and other constituent	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	2.1 mg
Sodium propionate (E281)	2.1 mg
Propylene glycol	
Docusate sodium	
Simeticone emulsion	
Aluminium magnesium silicate	
Citric acid monohydrate	
Xanthan gum	
Water, purified	

Thick white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves: dairy calves, beef suckler, bull beef).
Sheep (lambs).

3.2 Indications for use for each target species

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

3.3 Contraindications

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

For further information on use in cattle, please refer to the table in section 3.5 Special precautions for use, Special precautions for the protection of the environment.

3.4 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 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

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 including crop species.

For the mentioned environmental reasons the following restrictions on the use apply:

Cattle:

Veal calves	Not to be used in veal calves.
Dairy calves	Do not administer to dairy calves weighing more than 80 kg bodyweight. 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.
Suckler calves	Do not administer to suckler calves weighing more than 150 kg bodyweight.
Bull beef calves	Not to be used to treat bull beef calves less than 3 months old. Do not administer to bull beef calves weighing more than 150 kg bodyweight.

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.

3.6 Adverse events

Cattle and Sheep: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 a correct dosage, 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP51BC01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Cattle:
After oral administration of the product in cattle, toltrazuril is slowly absorbed. The maximal plasma concentration (c_{max} = 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.

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 section 3.5.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 12 months.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

J&M Veterinary Services Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10954/011/001

8. DATE OF FIRST AUTHORISATION

20/09/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/09/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).