SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacox 2.5 mg/ml Oral Suspension for Sheep and Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Diclazuril 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg
Microcrystalline cellulose and carmellose sodium	
Citric acid monohydrate	
Polysorbate 20	
Sodium hydroxide (for pH adjustment)	
Purified water	

A white to off-white homogenous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs)
Cattle (calves)

3.2 Indications for use for each target species

Lambs:
Prevention of clinical signs of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis*.

Calves:
Prevention of clinical signs of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.

3.3 Contraindications

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

3.4 Special warnings

If there is no recent and confirmed history of clinical coccidiosis, the presence of the disease in the flock or herd must be established before the product is used.

The preferred timing of treatment is directed by the known epidemiology of *Eimeria* spp. with treatment being most effective during the pre-patent phase of infection before clinical signs occur.

Calves: In certain cases, only a transient reduction of oocyst shedding may be achieved.

Suspected clinical cases of resistance to anticoccidials should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular antiprotozoal, an anticoccidial belonging to another pharmacological class and having a different mode of action should be used.
Cross-resistance between toltrazuril and diclazuril is possible and should be investigated. Use of diclazuril should be carefully considered when susceptibility testing has shown resistance to triazine-derivates because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all lambs in a group and all calves in a pen. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive fluid therapy is essential.

Preventative use of this veterinary product should be restricted to animals that have very high risk of infection.

Frequent and repeated use of antiprotozoals may lead to the development of resistance in the target parasite.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after administration of the product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Sheep (lambs) and Cattle (calves):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder (e.g. Diarrhoea[1,2]); Lethargy, Recumbency; Agitation; Neurological signs (e.g. Paresis)

[1] with possible presence of blood
[2] in some treated animals, even though oocyst excretion is reduced to a very low level.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interactions with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
Shake well before use.
The use of suitably calibrated measuring equipment is recommended to ensure accurate dosing. This is particularly important when administering small volumes.
To ensure a correct dosage, body weight should be determined as accurately as possible.
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 overdosing.
1 mg diclazuril per kg body weight (i.e. 1 ml of the veterinary medicinal product per 2.5 kg body weight), in a single oral administration.

Dosage Guide:

Body weight (Lambs and Calves)	Dose Volume 1 mg/kg
5.0 kg	2 ml
7.5 kg	3 ml
10.0 kg	4 ml
12.5 kg	5 ml
15.0 kg	6 ml
20.0 kg	8 ml
25.0 kg	10 ml
50.0 kg	20 ml
75.0 kg	30 ml
100.0 kg	40 ml
150.0 kg	60 ml
175.0 kg	70 ml
200.0 kg	80 ml

The oral suspension should be administered directly in the mouth with appropriate drenching equipment.

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

Sheep (lambs): No clinical signs of overdose were noted after administration of 5 times the recommended dose.
Cattle (calves): No clinical signs of overdose were noted after a single administration of 5 times the recommended dose. In case of repeated administration of 3 to 5 times the dose, on 3 consecutive days, a softening and a colour change (dark brown) of the faeces can be observed in some calves. These observations were transient and disappeared without specific treatment.

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

Meat and offal:
Sheep (lambs): zero days
Cattle (calves): zero days
Not authorised for use in animals producing milk for human consumption

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51BC03

4.2 Pharmacodynamics

Diclazuril is an anticoccidial of the benzeneacetonitrile group and has anticoccidial activity against *Eimeria* species. Depending on the coccidia species, diclazuril has a coccidiocidal effect on the asexual or sexual stages of the development cycle of the parasite. Diclazuril treatment will only have limited effect on the intestinal lesions caused by coccidial stages older than 16 days. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 weeks. This allows the animal to bridge the period of decrease of maternal immunity (observed at approximately 4 weeks of age).

4.3 Pharmacokinetics

The absorption of diclazuril in lambs is poor after administration of the oral suspension. Following a 1 mg/kg bodyweight dose in 2-3-week-old lambs a mean maximum concentration of 301 ng/ml was obtained around 16 hours after dosing. The elimination half-life was approximately 60 hours. The oral absorption of diclazuril decreases with the animals' age. *In-vitro* studies on sheep hepatocytes demonstrated that metabolic transformation of diclazuril is limited. This was equally observed in other animal species. Excretion occurs almost completely via the faeces.
When diclazuril is administered in oral suspension to calves, its absorption is poor. Following a 1 mg/kg bodyweight dose in young calves a mean maximum concentration of 117 ng/ml was obtained around 16 hours after dosing. The elimination half-life was approximately 15 hours.

Environmental properties

Diclazuril has been shown to be very persistent in soil.

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: 6 months

5.3 Special precautions for storage

Do not refrigerate or freeze. Protect from frost.

5.4 Nature and composition of immediate packaging

1 litre, 2.5 litre and 5 litre high density polyethylene container with polypropylene tamper-evident cap with an aluminium seal.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/3004

8. DATE OF FIRST AUTHORISATION

22 August 2024

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

August 2024

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).

Gavin Hall
Approved: 22 August 2024