PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {1L, 2.5L and 5L – HDPE Containers}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacox 2.5 mg/ml Oral Suspension for Sheep and Cattle

2. 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. PACKAGE SIZE

1 L
2.5 L
5 L

4. TARGET SPECIES

Sheep (lambs)
Cattle (calves)

5. INDICATIONS FOR USE

Indications for use

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

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

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

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.

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.

Pregnancy, lactation or lay:
Not applicable.

Interactions with other medicinal products and other forms of interaction:
None known.

Overdose:
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.

Special restrictions for use and special conditions for use:
Not applicable.

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

8. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral use.
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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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

11. WITHDRAWAL PERIODS

Withdrawal periods

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

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Do not refrigerate or freeze. Protect from frost.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/5005

Pack sizes

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.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Local representative and contact details to report suspected adverse reactions:
Cross Vetpharm Group UK Limited (Trading as Bimeda)
Unit 2, Bryn Cefni Industrial Park
Llangefni, LL77 7XA
United Kingdom
Tel: 01248 725 400

18. OTHER INFORMATION

Other information

Environmental properties
Diclazuril has been shown to be very persistent in soil.

POM-VPS

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by _____.
Shelf life after first opening the immediate packaging: 6 months.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 22 August 2024