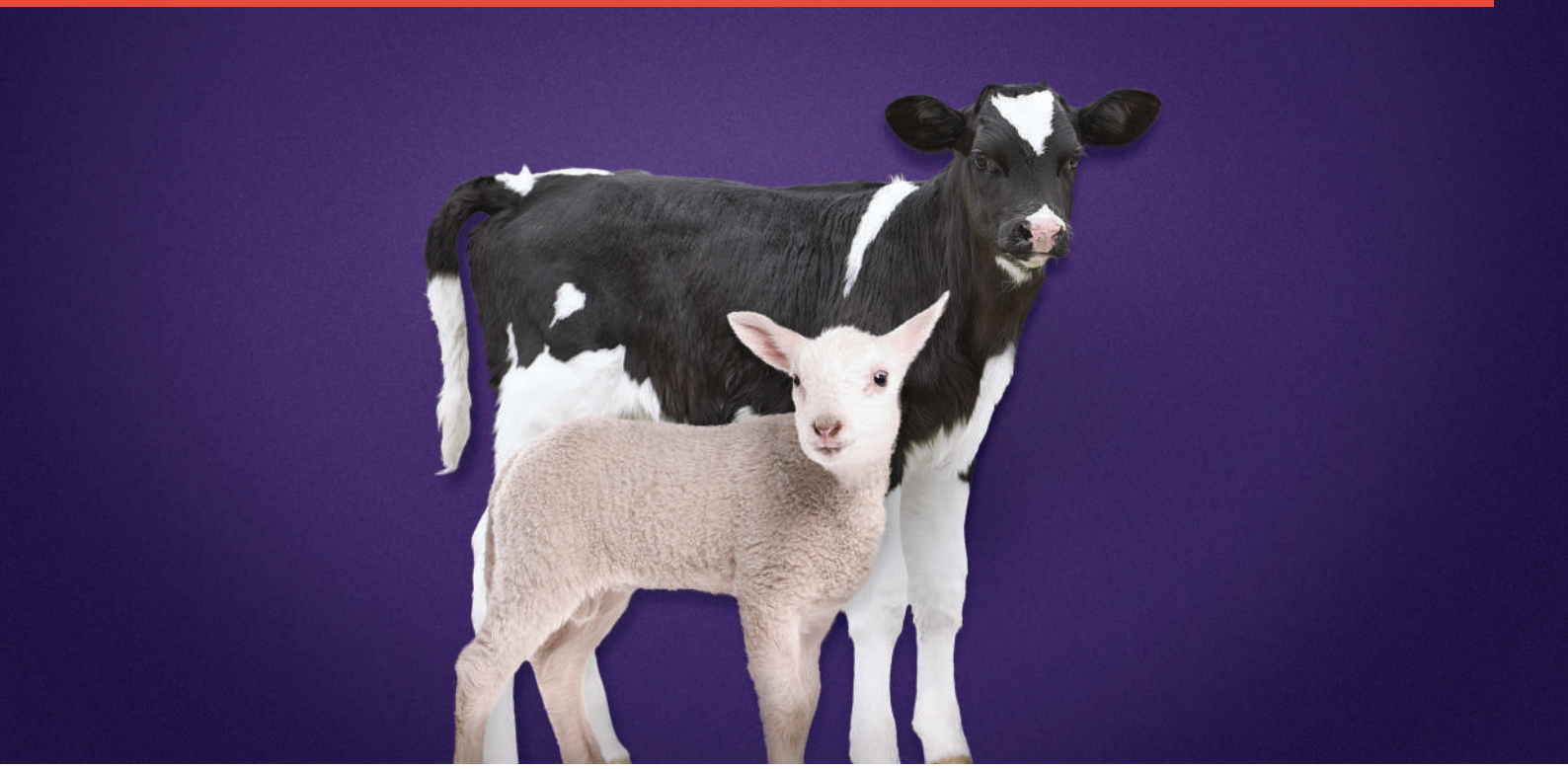
BIMACOX

Oral Suspension for Sheep and Cattle

Diclazuril 2.5 mg/ml

DATA SHEET



INDICATIONS

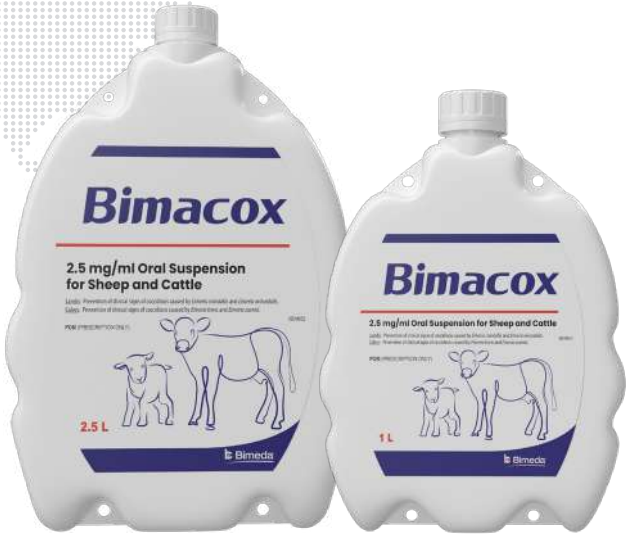
Lambs:
Prevention of clinical signs of coccidiosis caused by *Eimeria crandallis* and *Eimeria ovinoidalis.*

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

BENEFITS

- **Simple oral administration**
- **Licenced for lambs & calves**
- **Prevents clinical signs of key pathogenic coccidial species**
- **Zero meat withdrawal for flexibility**
- **Prevents clinical signs while allowing exposure & development of immunity**

LIST No	UNIT PACKAGE	CASE SIZE
1BIM360	1L	6
1BIM361	2.5L	12



See reverse for Administration & Dosage

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PRESENTATION
Oral Suspension.
A white to off-white homogenous suspension.

TARGET SPECIES
Sheep (lambs), Cattle (calves)

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

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.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)
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.

USE DURING PREGNANCY AND LACTATION OR LAY
Not applicable.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
None known.

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.

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.

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY
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.

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

ATCvet code: QP51BC03

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).

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.

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

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.

SPECIAL PRECAUTIONS FOR STORAGE
Do not refrigerate or freeze. Protect from frost.

PACK SIZES AUTHORISED
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.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIAL, IF ANY
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.

MARKETING AUTHORISATION HOLDER
Bimeda Animal Health Limited
Limited, Unit 2/3/4 Airton , Close, Tallaght, Dublin 24, Ireland

MARKETING AUTHORISATION NUMBER
VPA 22033/083/001

LEGAL CATEGORY
POM

A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website.

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.ie

Bimeda data sheet created: September 2024