1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diclacare 2.5 mg/ml Oral Suspension for lambs and calves

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	

White, oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs) and cattle (calves).

3.2 Indications for use for each target species

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

In 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

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

The preferred time of treatment depends on the development of the *Eimeria* spp. Suspected clinical cases of resistance to anticoccidials should be further investigated using appropriate tests (e.g. Faecal Egg

Count Reduction Test). If the results of the test(s) confirm resistance to a particular anticoccidial, therapy should be continued with an anticoccidial belonging to another pharmacological class and having a different mode of action.

If there is no recent and confirmed history of clinical coccidiosis, the presence of coccidia in the flock or herd should be confirmed by faecal sampling prior to treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all lambs in the flock and all calves in a pen.

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

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required as diclazuril has no antimicrobial activity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Esters of parahydroxybenzoic acid may cause allergic reactions (possibly delayed). People with known hypersensitivity to parabens should administer the veterinary medicinal product with caution.

Wash hands after administration of the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Target species: Lambs and calves

Undetermined frequency (cannot be estimated from the available data)	Diarrhoea[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lethargy Gastrointestinal disorders (such as blood in faeces) Neurological disorders (agitation, recumbency, paresis)

[1]Some treated animals may show signs of clinical disease 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 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

Oral use.

In lambs and calves:
1 mg diclazuril per kg body weight (1 ml of the oral suspension per 2.5 kg body weight), as a single oral administration.

Shake well before use.

The use of suitably calibrated measuring equipment is recommended.

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 bodyweight and dosed accordingly, in order to avoid under- or overdosing.

The oral suspension should be administered with a drenching gun. Appropriate drenching equipment should be used to allow accurate dosing. This is particularly important when administering small volumes.

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

In lambs: no side effects were noted after administration of 5 times the therapeutic dose.
In calves: no side effects were noted after administration of 5 times the therapeutic dose. After the administration of 3 to 5 times the therapeutic dose on 3 consecutive days, soft and dark (dark brown) 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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51AJ03.

4.2 Pharmacodynamics

Diclazuril is an anticoccidial of the benzeneacetonitrile group with no antimicrobial activity 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 parasitic 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. Maximum concentrations in plasma are reached about 24 hours after dosing. The absorption decreases with the animals' age. The elimination half-life is about 30 hours. *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.
The absorption of diclazuril in calves is poor after administration of the oral suspension.

Environmental properties

Diclazuril is 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

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

5.4 Nature and composition of immediate packaging

High density polyethylene bottle, closed with polypropylene screw cap with induction disk.

Package sizes
Box with 1 litre bottle with harness and spouted cap
Box with 2.5 litre bottle with harness and spouted cap
Box with 5 litre bottle with harness and spouted cap

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

LABORATORIOS KARIZOO, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10786/010/001

8. DATE OF FIRST AUTHORISATION

28/03/2024

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

13/09/2024

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).