Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 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:	
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

White, oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Ovine (lambs) and bovine (calves).

4.2 Indications for use, specifying the target species

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

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

4.3 Contraindications

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

4.4 Special warnings for each target species

Avoid underdosing which may be due to underestimation of body weight, misadministration of the product or lack of calibration of the dosing device (if any).
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.

4.5 Special precautions for use

Special precautions for use in animals
The preferred timing of treatment is directed by the known epidemiology of *Eimeria spp.* and the presence of coccidia in the flock or herd should be confirmed by faecal sampling prior to treatment, if there is no recent and confirmed history of clinical coccidiosis.

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
Wash hands after administration of the product.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, adverse events involving gastrointestinal disorders (such as diarrhoea, with possible presence of blood), lethargy and/or neurological troubles (agitation, recumbency, paresis...) have been reported.

Some treated animals may show signs of clinical disease (diarrhoea) even though oocyst excretion is reduced to a very low level.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Shake well before use.

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 oral suspension per 2.5 kg body weight), in a single oral administration.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In lambs: no signs of overdose were noted after administration of 5 times the recommended dose.
In calves: no 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.

4.11 Withdrawal period(s)

Meat and offal:
Lambs: zero days
Calves: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, Triazines
ATCVet Code: QP51AJ03

5.1 Pharmacodynamic properties

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 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).

5.2 Pharmacokinetic particulars

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.

When diclazuril is administered in oral suspension to calves, its absorption is poor.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Microcrystalline cellulose (E460)
Carboxymethylcellulose sodium (E466)
Citric acid monohydrate (E330)
Polysorbate 20 (E432)
Sodium hydroxide (E524)
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

Nature of the container
High density polyethylene bottle
High density polyethylene screw cap
High density polyethylene dosing cap

Commercial packs
Box with 200 ml container with harness and spouted cap
Box with 1 litre container with harness and spouted cap

Box with 2.5 litre container with harness and spouted cap
Box with 5 litre container with harness and spouted cap

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/285/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 February 2000
Date of last renewal: 24 October 2008

10 DATE OF REVISION OF THE TEXT

November 2020