

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Diclazuril Elanco 2.5 mg/ml Oral Suspension for lambs and calves.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**

Diclazuril	2.5 mg
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**Excipients:**

Methyl parahydroxybenzoate (E218)	1.8 mg
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Propyl parahydroxybenzoate (E216)	0.2 mg
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For a full list of excipients, see section 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

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

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).

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 anthelmintic, 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.

##### 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)

None known.

#### 4.7 Use during pregnancy, lactation or lay

Not applicable.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

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.

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

## 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 properties

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 (E216)

Microcrystalline cellulose and carboxymethylcellulose sodium

Citric acid monohydrate

Polysorbate 20

Sodium hydroxide

Purified water

### 6.2 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 closure

High density polyethylene nozzle closure.

#### Commercial pack(s)

Box with 200 ml container with harness and spouted cap

Box with 1 L container with harness and spouted cap

Box with 2.5 L container with harness and spouted cap

Box with 5 L 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

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

## 7 MARKETING AUTHORISATION HOLDER

Elanco Animal Health  
Eli Lilly and Company Limited  
Priestly Road  
Basingstoke  
Hampshire  
RG24 9NL  
England

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10047/030/001

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th June 2013

## 10 DATE OF REVISION OF THE TEXT