1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dycoxan 2.5 mg/ml Oral Suspension for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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	
Carmellose Sodium	
Polysorbate 20	
Sodium Hydroxide	
Purified water	

A white to off-white oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs)
Cattle (calves)

3.2 Indications for use for each target species

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

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

3.3 Contraindications

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

3.4 Special warnings

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

Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all lambs of the flock and all calves in a pen. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.

The preferred timing of treatment is directed by the known epidemiology of *Eimeria* spp. and 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.

In certain cases, only a transient reduction of oocyst shedding may be achieved. Suspected clinical cases of resistance to anticoccidials should be further investigated and where evidence strongly suggest resistance to a particular antiprotozoal, an anticoccidial belonging to another pharmacological class and having a different mode of action should be used.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Lambs
On rare occasions, in highly susceptible lambs e.g. where they have been housed for long periods of time before being turned out onto heavily contaminated pasture, a severe scour has been seen shortly after dosing. In such cases, fluid therapy is essential.

Calves
Clinical coccidiosis generally occurs late in the parasite's life cycle after most of the damage to the calf's intestine has already been done. This severely damaged intestine can easily be infected by secondary bacteria and/or other agents. In cases of acute clinical coccidiosis treated with the veterinary medicinal product, fluid therapy is essential. Symptoms of clinical disease may remain obvious in some calves treated with the veterinary medicinal product, even though oocyst excretion is reduced to a very low level, and overall prevalence of diarrhoea is decreased.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 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] Some treated animals may show signs of clinical disease (diarrhoea) 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 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.

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.

If a satisfactory response is not observed, then further advice should be sought from your veterinary surgeon, and the cause of the condition should be reviewed. It is good practice to ensure the cleanliness of calf housing.

Dosage guide: 1 mg diclazuril per kg bodyweight (equivalent to 1 ml of the veterinary medicinal product per 2.5 kg bodyweight) as a single oral administration.

Bodyweight (kg)	Dose Volume (ml)
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

Lambs:
A single oral administration of 1 mg diclazuril per kg bodyweight or 1 ml of veterinary medicinal product per 2.5 kg bodyweight at about 4-6 weeks of age at the time that coccidiosis can normally be expected on the farm.

Under conditions of high infection pressure, a second treatment may be indicated about 3 weeks after the first dosing.

Calves:
A single administration of 1 mg diclazuril per kg bodyweight or 1 ml of veterinary medicinal product per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high-risk environment.

Method of administration:

Shake well before use.
The use of suitably calibrated measuring equipment is recommended.
The veterinary medicinal product 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)

Diclazuril oral suspension was given to lambs as a single dose up to 60 times the therapeutic dose. No adverse clinical effects were reported.
No adverse effects were noted either at 5 times the therapeutic dose administered four consecutive times with a 7-day interval.

In calves, the veterinary medicinal product was tolerated when administered up to five times the recommended dose rate.

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

Meat and offal:
Sheep (lambs): zero days.
Cattle (calves): zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP51AJ03

4.2 Pharmacodynamics

Diclazuril is an anticoccidial of the benzene acetonitrile group and has an 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. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 to 3 weeks after administration. This allows the lambs to bridge the period of decrease of maternal immunity (observed at approximately 4 weeks of age) and calves to reduce the infection pressure of their environment.

4.3 Pharmacokinetics

The absorption of diclazuril when administered as an oral suspension to lambs and calves is poor. In lambs, peak plasma concentrations are reached about 24 hours after dosing. The absorption decreases with the age of the lambs. The elimination half-life is about 30 hours.

In calves, kinetic profiles have been studied after administration of a single dose of 5 mg diclazuril per kg body weight and after dosing for 3 consecutive days at respectively 1 mg, 3 mg and 5 mg diclazuril per kg body weight. Following the single dose of 5 mg peak plasma concentrations in the range of 21 to 75 ng/ml were reached after 8 to 24 hours. Thereafter the concentrations decreased with a half-life of 16 hours to concentrations below 10 ng/ml after 48 hours. Following the 3 consecutive daily doses of 1 mg diclazuril per kg body weight, mean peak plasma concentrations of 65.6 ng/ml were reached 10.5 hours after the last dose. Thereafter the concentrations decreased with a half-life of 22 hours. The $AUC_{0\text{-}96\ h}$ was 2127 h.ng/ml. Comparison with the profiles obtained after the multiple doses

indicated dose proportionality and linearity. The time to reach peak plasma concentrations and the subsequent depletion half-life were independent of the dose. In vitro studies in ovine and bovine hepatocytes indicated that the metabolic transformation of diclazuril is very limited, as was also observed for other species. In vivo studies in a number of animal species have also demonstrated that diclazuril is not excreted and excreted virtually completely unchanged with the faeces.

Environmental properties

Diclazuril has been shown to be 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: 2 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

200 ml: PET bottle with child resistant tamper evident HDPE cap with LDPE lining.
1 litre, 2.5 litre and 5 litre: high density polyethylene bottle with polypropylene tamper-evident cap with Alu seal.

Pack sizes:
Cardboard box with 1 bottle of 200 ml
Cardboard box with 1 bottle of 1 l
Cardboard box with 1 bottle of 2.5 l
Cardboard box with 1 bottle of 5 l

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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/122/001

8. DATE OF FIRST AUTHORISATION

04/05/2018

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

03/03/2026

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).