B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Diacox 2.5 mg/ml Oral Suspension for Sheep and Cattle (ES, CY)
Dycoxan 2.5 mg/ml Oral Suspension for Sheep and Cattle (FR)
Coxicert 2.5 mg/ml Oral Suspension for Sheep and Cattle (UK NI)
Fendicox 2.5 mg/ml Oral Suspension for Sheep and Cattle (NL, BE)

2. Composition

Each ml contains:

Active substance:
Diclazuril 2.5 mg

Excipients:
Methyl Parahydroxybenzoate (E218) 1.8 mg
Propyl Parahydroxybenzoate 0.2 mg

A white to off-white oral suspension.

3. Target species

Sheep (lambs)
Cattle (calves)

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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 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.

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.

Overdose:
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.

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

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.

The veterinary medicinal product should be administered with a drenching gun.

Dosage guide: 1 mg diclazuril per kg bodyweight (equivalent to 1 ml of 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.

9. Advice on correct administration

Shake well before use.

The use of suitably calibrated measuring equipment is recommended.

Appropriate drenching equipment should be used to allow 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 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.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton/bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

Cardboard box with a bottle of 5 l

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea, Co. Galway,
H62 FH90
Ireland

<Local representatives <and contact details to report suspected adverse events>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder>.

17. Other information

Environmental properties: Diclazuril has been shown to be very persistent in soil.