A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

{Carton/Label for 200 ml, 1 L, 2.5 L and 5 L bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dycoxan 2.5 mg/ml Oral Suspension for sheep and cattle.
Diacox 2.5 mg/ml Oral Suspension for sheep and cattle (DE, FR)
Rumicox 2.5 mg/ml Oral Suspension for sheep and cattle (ES, IT, PT)
Diclazuril

2. STATEMENT OF ACTIVE SUBSTANCES

1ML contains Diclazuril 2.5 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

200 ml
1 L
2.5 L
5 L

5. TARGET SPECIES

Sheep (Lambs) and Cattle (Calves)

6. INDICATION(S)

For OTC products:

In Sheep (lambs):
Prevention of clinical signs of coccidiosis caused by Eimeria crandallis and Eimeria ovinoidalis sensitive to diclazuril.

In Cattle (calves):
Prevention of clinical signs of coccidiosis caused by Eimeria bovis and Eimeria zuernii sensitive to diclazuril.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

Method of administration

Shake well before use.

The product 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.

DOSAGE GUIDE:

Bodyweight (Lambs and Calves)	**Dose Volume 1 mg/kg**
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

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 6 months
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Dycoxan 2.5 mg/ml Oral Suspension for sheep and cattle
Diacox 2.5 mg/ml Oral Suspension for sheep and cattle (DE, FR)
Rumicox 2.5 mg/ml Oral Suspension for sheep and cattle (ES, IT, PT)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dycoxan 2.5 mg/ml Oral Suspension for sheep and cattle
Diacox 2.5 mg/ml Oral Suspension for sheep and cattle (DE, FR)
Rumicox 2.5 mg/ml Oral Suspension for sheep and cattle (ES, IT, PT)
Diclazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Oral suspension.
White to off-white suspension

1ml contains
Active substance:
Diclazuril 2.5 mg

Preservatives
Methyl Parahydroxybenzoate (E218) 1.8 mg
Propyl Parahydroxybenzoate 0.2 mg
Oral suspension

4. INDICATION(S)

Lambs: Prevention of clinical signs of coccidial infestations in lambs 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. ADVERSE REACTIONS

In very rare cases, side effects linked to gastrointestinal disorders such as diarrhea, lethargy and / or neurological disorders (agitation, decubitus, paresis) have been noticed.

Some treated animals may show signs of clinical disease (diarrhea), even if the excretion of oocysts is reduced to a very low level.

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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep (lambs) and cattle (calves)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use only.

1 mg diclazuril per kg bodyweight (equivalent to 1 ml of the oral suspension per 2.5 kg bodyweight) as a single oral administration.

Lambs:
A single oral administration of 1 mg diclazuril per kg bodyweight or 1 ml the product oral suspension 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 the product oral suspension per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high risk environment.

To ensure the correct dosage, bodyweight should be determined as accurately as possible.

DOSAGE GUIDE:

Bodyweight (Lambs and Calves)	**Dose Volume 1 mg/kg**
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

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.

Method of administration
Shake well before use.
The product 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.

9. ADVICE ON CORRECT ADMINISTRATION

See point 8.

10. WITHDRAWAL PERIOD(S)

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 after the expiry date (EXP) stated on the carton/bottle.
The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 6 months

12. SPECIAL WARNING(S)

Special warnings for each target species

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

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.

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 product, fluid therapy is essential. Symptoms of clinical disease may remain obvious in some calves treated with the product, even though oocyst excretion is reduced to a very low level, and overall prevalence of diarrhoea is decreased.

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

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

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.

Use during pregnancy and lactation:
Not applicable

Overdose (symptoms, emergency procedures, 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 product was tolerated when administered up to five times the recommended dose rate.

Interaction with other medicinal products and other forms of interaction:
None known

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

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 200 ml, 1L, 2.5L and 5L

Not all pack sizes may be marketed.

For Animal Treatment Only.