

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

200ml, 1L, 2.5L and 5L CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension
Diclazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 2.5 mg diclazuril
Also contains preservatives: 1.8 mg methyl parahydroxybenzoate (E218), and 0.2 mg propyl parahydroxybenzoate

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

200 ml
1 Litre
2.5 Litres
5 Litres

5. TARGET SPECIES

Sheep (lambs) and cattle (calves)

6. INDICATION(S)

Anticoccidial oral drench
For the treatment and prevention of coccidial infections in lambs caused, in particular by the more pathogenic *Eimeria* species, *E.crandallis* and *E.ovinoidalis*.
To aid in the control of coccidiosis in calves caused by *Eimeria bovis* and *Eimeria zuernii*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use only.
To ensure the correct dosage, bodyweight should be determined as accurately as possible.

LAMBS

Therapeutic use: 1 mg diclazuril per kg bodyweight, in a single administration.
Prevention use: 1 mg diclazuril per kg bodyweight or 1 ml of the 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

To aid in the control of coccidiosis caused by *E.bovis* and *E.zuernii*:

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

It is advocated 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. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 to 3 weeks after administration.

For oral use in lambs and calves

Bodyweight	Volume
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

Method of Administration

SHAKE WELL BEFORE USE

After using draw-off cap, re-close with original cap.

The product should be used by careful administration with a drenching gun.

Appropriately graduated drenching equipment must be used to allow accurate administration of the required dose volume. This is particularly important when administering small volumes.

8. WITHDRAWAL PERIOD(S)

Meat and offal: Lambs and calves: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

SPECIAL WARNINGS IN ANIMALS:

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 and the use of a sulphonamide should be considered. It is also important to consider other potential pathogens that may be playing a role e.g. *Cryptosporidium*, *Nematodirus*, Rotavirus, *Giardia* and *E.coli*.

In the event of any stress factors (e.g. cold weather, other diseases) or high challenge (e.g. warm wet weather, inability to move lambs from infected pastures after dosing) the timing of the doses may need to be adjusted.

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 and the use of an antibiotic should be considered. 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.

USER WARNINGS:

Wash hands after use.

10. EXPIRY DATE

Use by end: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 30 °C.
PROTECT FROM FROST

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

FOR ANIMAL TREATMENT ONLY.

POM-VPS

UK authorised veterinary medicinal product.
To be supplied only on veterinary prescription.

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

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4647

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

OTHER INFORMATION

Marketing Authorisation Holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributed by:

Mole Valley Farmers, Exmoor House, Lime Way, Pathfields Business Park, South
Molton, Devon, EX36 3LH
Tel: 01769 576415

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

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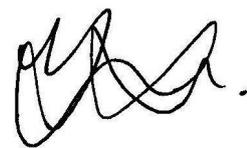
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