

**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.

<b>15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
---

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

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
--

Vm 01708/4647

<b>17. MANUFACTURER'S BATCH NUMBER</b>
--

Batch No: {number}

<b>OTHER INFORMATION</b>
--------------------------

**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**

**200ml, 1L, 2.5L and 5L BOTTLE**

**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 or 1 ml of the product per 2.5 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.

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

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.

### **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**

### **User warning**

Wash hands after use.

### **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.

### **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  
Buckinghamshire  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4647

**17. MANUFACTURER'S BATCH NUMBER**

Batch No: {number}

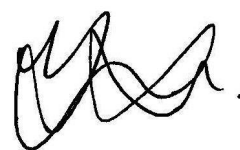
**OTHER INFORMATION**

**Marketing Authorisation Holder:**

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

**Distributed by:**

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



Approved: 06 October 2020