PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard Box – 200 ml presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. PACKAGE SIZE

200 ml

4. TARGET SPECIES

Sheep (lambs) and cattle (calves).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

Withdrawal period: Lambs and calves:
Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Protect from frost.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5037
Vm 06376/3039

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – Label (Front and Back label) 200 ml presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. TARGET SPECIES

Sheep (lambs) and cattle (calves).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.
Shake well before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Lambs and calves:
Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Molecoxan 2.5 mg/ml Oral Suspension

2. Composition

Each ml contains:

Active substance:
Diclazuril 2.5 mg

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

White, homogeneous suspension.

3. Target species

Sheep (lambs) and cattle (calves).

4. Indications for use

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*.

5. Contraindications

None.

6. Special warnings

None.

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 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 veterinary medicinal 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 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.

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

Overdose:
The veterinary medicinal product 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.

Major incompatibilities:
None known.

7. Adverse events

Sheep (lambs) and cattle (calves):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal signs (e.g. Diarrhoea[1,2]); Lethargy, Recumbency; Agitation; Neurological signs (e.g. Paresis).

[1] with possible presence of blood.
[2] in some treated animals, 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Oral use.

Lambs:
Therapeutic use: 1 mg diclazuril per kg bodyweight or 1 ml of the veterinary medicinal product per 2.5 kg bodyweight, as a single administration.

Preventative use: 1 mg diclazuril per kg bodyweight or 1 ml of the 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:
To aid in the control of coccidiosis: 1 mg diclazuril per kg bodyweight or 1 ml of the veterinary medicinal product per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high-risk environment.
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.

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

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.

9. Advice on correct administration

Shake well before use.
To ensure a correct dosage, bodyweight should be determined as accurately as possible.
After using the draw-off cap, re-close the container with the original cap.
The veterinary medicinal product should be used by careful administration with a drenching gun.
Appropriately graduated drenching equipment must be used to allow accurate dosing. This is particularly important when administering small volumes.

10. Withdrawal periods

Lambs and calves:
Meat and offal: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C.
Protect from frost.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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

Vm 06376/5037
Vm 06376/3039

Pack sizes:
Cardboard box with 1 x 200 ml bottle.
Bottle of 1 litre, 2.5 litres or 5 litres.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
Igoville 27460
France

Local representative and contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom
Tel.: +44 (0)1908 685685

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

17. Other information

POM-VPS

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE -FRONT LABEL – 1 Litre, 2.5 Litre and 5 Litre presentations

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. TARGET SPECIES

Sheep (lambs) and cattle (calves).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.
Shake well before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Lambs and calves:
Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE (OUTER) PACKAGE – 1 Litre, 2.5 Litre and 5 Litre presentations – BACK LABEL -Base label and front cover of concertina label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Diclazuril 2.5 mg/ml

3. PACKAGE SIZE

1 Litre
2.5 Litres
5 Litres

4. TARGET SPECIES

Sheep (lambs) and cattle (calves).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Lambs and calves:
Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
Protect from frost.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5037
Vm 06376/3039

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Molecoxan 2.5 mg/ml Oral Suspension

2. Composition

Each ml contains:

Active substance:
Diclazuril 2.5 mg

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

White, homogeneous suspension.

3. Target species

Sheep (lambs) and cattle (calves).

4. Indications for use

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*.

5. Contraindications

None.

6. Special warnings

None.

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 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 veterinary medicinal 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 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.

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

Overdose:
The veterinary medicinal product 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.

Major incompatibilities:
None known.

7. Adverse events

Sheep (lambs) and cattle (calves):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal signs (e.g. Diarrhoea[1,2]); Lethargy, Recumbency; Agitation; Neurological signs (e.g. Paresis).

[1] with possible presence of blood.
[2] in some treated animals, 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Oral use.

Lambs:
Therapeutic use: 1 mg diclazuril per kg bodyweight or 1 ml of the veterinary medicinal product per 2.5 kg bodyweight, as a single administration.

Preventative use: 1 mg diclazuril per kg bodyweight or 1 ml of the 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:
To aid in the control of coccidiosis: 1 mg diclazuril per kg bodyweight or 1 ml of the veterinary medicinal product per 2.5 kg bodyweight, administered as a single dose, 14 days after moving into a potentially high-risk environment.
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.

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

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.

9. Advice on correct administration

Shake well before use.
To ensure a correct dosage, bodyweight should be determined as accurately as possible.
After using the draw-off cap, re-close the container with the original cap.
The veterinary medicinal product should be used by careful administration with a drenching gun.
Appropriately graduated drenching equipment must be used to allow accurate dosing. This is particularly important when administering small volumes.

10. Withdrawal periods

Lambs and calves:
Meat and offal: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C.
Protect from frost.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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

Vm 06376/5037
Vm 06376/3039

Pack sizes:
Cardboard box with 1 x 200 ml bottle.
Bottle of 1 litre, 2.5 litres or 5 litres.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
Igoville 27460
France

Local representative and contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom
Tel.: +44 (0)1908 685685

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

17. Other information

POM-VPS

Gavin Hall

Approved 08 March 2026