SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molecoxan 2.5 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Diclazuril 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate	0.2 mg
Microcrystalline cellulose and carmellose sodium	
Citric acid monohydrate	
Polysorbate 20 (E432)	
Sodium hydroxide (E524)	
Water, purified	

White, homogeneous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs) and cattle (calves).

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
For oral use only.
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.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

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

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.
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 the draw-off cap, re-close the container with the original cap. The veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Lambs and calves:
Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51BC03.

4.2 Pharmacodynamics

Diclazuril is an anticoccidial of the benzene acetonitrile group and has an anticoccidial activity against *Eimeria* species. Depending on the coccidia species, diclazuril has a coccidiocidal effect on the asexual or sexual stages of the development cycle of the parasite. Treatment with diclazuril causes interruption of the coccidial cycle and of excretion of oocysts for approximately 2 to 3 weeks after administration. This allows the lambs to bridge the period of decrease of maternal immunity (observed at approximately 4 weeks of age) and calves to reduce the infection pressure of their environment.

4.3 Pharmacokinetics

After administration of the oral suspension, the absorption of diclazuril in lambs is poor. The maximum concentration in plasma is reached between 24 hours and 48 hours after dosing. The elimination half-life is about 30 hours. The metabolism of diclazuril was studied in vitro using sheep hepatocytes. Studies indicate that at 24 hours after administration, the concentration in edible tissues are far below the Acceptable Daily Intake. As a consequence, there is no need to establish Maximum Residue Limits or to determine a Withdrawal Period.

The absorption of diclazuril when administered as an oral suspension to lambs and calves is poor. In lambs, peak plasma concentrations are reached about 24 hours after dosing. The absorption decreases with the age of the lambs. The elimination half-life is about 30 hours. In calves, kinetic profiles have been studied after administration of a single dose

of 5 mg diclazuril per kg bodyweight and after dosing for 3 consecutive days at respectively 1 mg, 3 mg and 5 mg diclazuril per kg bodyweight. Following the single dose of 5 mg peak plasma concentrations in the range of 21 to 75 ng/ml were reached after 8 to 24 hours. Thereafter the concentrations decreased with a half-life of 16 hours to concentrations below 10 ng/ml after 48 hours. Following the 3 consecutive daily doses of 1 mg diclazuril per kg bodyweight, mean peak plasma concentrations of 65.6 ng/ml were reached 10.5 hours after the last dose. Thereafter the concentrations decreased with a half-life of 22 hours. The $AUC_{0\text{-}96\ h}$ was 2127 h.ng/ml. Comparison with the profiles obtained after the multiple doses indicated dose proportionality and linearity. The time to reach peak plasma concentrations and the subsequent depletion half-life were independent of the dose. Following an oral dose of 5 mg diclazuril per kg body weight only low concentrations of diclazuril distribute to the edible tissues which is another indication of the poor bioavailability. *In vitro* studies in ovine and bovine hepatocytes indicated that the metabolic transformation of diclazuril is very limited, as was also observed for other species. *In vivo* studies in a number of animal species have also demonstrated that diclazuril is not excreted and excreted virtually completely unchanged with the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

200 ml, 1 litre, 2.5 litre or 5 litre high-density polyethylene bottle, closed with a high-density polypropylene cap (screw fit, tamper evident) with a polyethylene induction-sealed liner. Each bottle is supplied with a polypropylene draw-off cap.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 06376/5037
Vm 06376/3039

8. DATE OF FIRST AUTHORISATION

29 July 2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved 08 March 2026