SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance*:*	**mg/ml**
Diclazuril	2.5

Excipients*:*

Methyl Parahydroxybenzoate (E218)	1.8
Propyl Parahydroxybenzoate	0.2

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
White, homogeneous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the 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*.

4.3 Contraindications

None.

4.4 Special warnings

None.

4.5 Special precautions for use

i. Special precautions for use in animals

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*.

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 Vecoxan, 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 Vecoxan, even though oocyst excretion is reduced to a very low level, and overall prevalence of diarrhoea is decreased.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None reported.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

Lambs:
Therapeutic use: 1 mg diclazuril per kg bodyweight or 1 ml Vecoxan oral suspension per 2.5 kg bodyweight, as a single administration.

Preventative use: 1 mg diclazuril per kg bodyweight or 1 ml Vecoxan 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:
To aid in the control of coccidiosis: 1 mg diclazuril per kg bodyweight or 1 ml Vecoxan oral suspension 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.

Method of administration
Shake well before use.
After using draw-off cap, re-close container with original cap. Vecoxan 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Vecoxan 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.

4.11 Withdrawal period(s)

Meat and offal:
Lambs: zero days
Calves: zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, triazine derivatives

ATCvet code: QP51AJ03

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

After administration of the oral suspension, the absorption of diclazuril in lambs is poor. The maximum concentration in plasma is reached between 24 h and 48 h 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 body weight and after dosing for 3 consecutive days at respectively 1 mg, 3 mg and 5 mg diclazuril per kg body weight. 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 an 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 body weight, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Microcrystalline Cellulose
Carboxymethylcellulose Sodium
Citric Acid Monohydrate
Polysorbate 20

Sodium Hydroxide (for pH adjustment)
Water, Purified

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

200 ml, 1 litre, 2.5 litre and 5 litre high density polyethylene bottle with high density polyethylene cap (screw fit, tamper evident) with white PVDC coated paper insert.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 43877/4005

9. DATE OF FIRST AUTHORISATION

05 April 2016

10. DATE OF REVISION OF THE TEXT

April 2016

Approved: 05/04/2016