

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml Oral Suspension
Diclazuril

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Diclazuril 2.5 mg

Excipients:

Methyl Parahydroxybenzoate (E218) 1.8 mg

Propyl Parahydroxybenzoate 0.2 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

5 litres

5. TARGET SPECIES

Sheep (lambs) and cattle (calves)

6. INDICATION(S)

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*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

8. WITHDRAWAL PERIOD

Meat and offal:

Lambs: zero days

Calves: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

Exp.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

Protect from frost.

Keep the container in the outer carton

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

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

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

For animal treatment only

POM-VPS

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 43877/4009

17. MANUFACTURER’S BATCH NUMBER

Lot.

Manufactured by Elanco Animal Health
Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

Adverse events should be reported to the MAPI holder. To report an adverse event, ring
[UK telephone number]

PACKAGE LEAFLET FOR:

Vecoxan 2.5 mg/ml Oral Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

Marketing Authorisation Holder:

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

Manufacturer for batch release:

Lusomedicamenta Sociedade Técnica Farmacéutica, SA
Estrada Consiglieri Pedroso, 69 - B, Queluz de Baixo
2730-055 Barcarena
Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vecoxan 2.5 mg/ml Oral Suspension
Diclazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml of white, homogeneous oral suspension contains:

Active substance:	mg
Diclazuril	2.5

Excipients:

Methyl Parahydroxybenzoate (E218)	1.8
Propyl Parahydroxybenzoate	0.2

4. INDICATION(S)

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*.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

None reported. If you notice any serious effects or other effects please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep (lambs) and cattle (calves)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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 container with original cap. Vecoxan oral suspension 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.

9. WITHDRAWAL PERIOD(S)

Meat and offal:

Lambs: zero days

Calves: zero days

10. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

Protect from frost.

Keep the container in the outer carton.

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

11. SPECIAL WARNING(S)

For Animal Treatment Only

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.

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

Wash hands after use

Overdose (symptoms, emergency procedures, antidotes)

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.

12. 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.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2016

14. OTHER INFORMATION>

Nature and composition of immediate packaging

5 litre high density polyethylene bottle in a carton.

POM-VPS

Vm 43877/4009

Manufactured by Elanco Animal Health

Procured from within the EU and repackaged by the licence holder:

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

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Approved: 02/09/2016

