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Vecoxan® 2.5 mg/ml Oral Suspension

Species: Cattle, Sheep

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Antiprotozoals, Coccidiocides

Active ingredient: Diclazuril

Product: Vecoxan® 2.5 mg/ml Oral Suspension

Product index: Vecoxan®

Cattle - meat: Zero days

Sheep - meat: Zero days

Incorporating:

Qualitative and quantitative composition

Active substance*:* mg/ml

Diclazuril 2.5

Excipients*:*

Methyl Parahydroxybenzoate 1.8

Propyl Parahydroxybenzoate 0.2

For the full list of excipients, see section “Pharmaceutical particulars”.

Pharmaceutical form

Oral suspension.

White, homogeneous suspension

Clinical particulars

Target Species

Sheep and cattle

Indications for use

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*.

Contraindications

None.

Special warnings for each target species

None.

Special precautions for use

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.

Operator warnings

Wash hands after use.

Adverse Reactions

None reported.

Use during pregnancy or lactation

Not applicable.

Interactions

None known.

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.

Overdose

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.

Withdrawal periods

Meat and offal:

Lambs: zero days

Calves: zero days

Pharmacological particulars

ATC Vet Code: QP51AJ03

Pharmacotherapeutic group:

Antiprotozoals, triazine derivatives

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.

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 AUC0-96 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.

Pharmaceutical particulars

Excipients

Methyl Parahydroxybenzoate

Propyl Parahydroxybenzoate

Microcrystalline Cellulose

Carboxymethylcellulose Sodium

Citric Acid Monohydrate

Polysorbate 20

Sodium Hydroxide (for pH adjustment)

Water, Purified

Major incompatibilities

None known.

Shelf life

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

Special precautions for storage

Do not store above 30 °C.

Protect from frost.

Immediate packaging

200 ml, 1 litre, 2.5 litre and 5 litre high density polyethylene bottle with high density polypropylene cap (screw fit, tamper evident) with a polyethylene induction sealed liner.

Pack sizes:

Cardboard box containing a 200 ml bottle with a high-density polypropylene draw-off cap.

1, 2.5 or 5 Litre bottle with a high-density polypropylene draw-off cap.

Not all pack sizes may be marketed.

Disposal

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

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V., represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK(GB): Vm 06376/5039

UK(NI): Vm 06376/3041

Significant changes

Date of the first authorisation or date of renewal

03 February 1999

Date of revision of the text

March 2025.

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-VPS

GTIN

GTIN description:--

GTIN:--