Label **Use/Dose**

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FLUKIVER

Elanco

Closantel (as closantel sodium) Oral Suspension 50 mg/mL

FOR VETERINARY USE ONLY

DIN 02449293

Active Ingredient: closantel sodium

Medicinal ingredient per mL: 50 mg/mL closantel (5% w/v)

Indication:

For the treatment of *Haemonchus contortus* (Barber Pole worm) infection in sheep and lambs.

Dosage and Administration:

1 mL of Flukiver per 5 kg bodyweight (i.e., 10 mg closantel per kg bodyweight)

Bodyweight	Dose
Up to 5 kg	1 mL
10 kg	2 mL

20 kg	4 mL
30 kg	6 mL
40 kg	8 mL
50 kg	10 mL
60 kg	12 mL
70 kg	14 mL
80 kg	16 mL

Give orally as a drench. Suitable for use with most types of standard drenching equipment.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
SHAKE WELL BEFORE USING.
Do not mix with other products.

Directions for use:

This product is labelled for the treatment of *Haemonchus contortus* (Barber Pole worm) infection only. Treatment given without a diagnosis of haemonchosis could be mistaken as treatment failure. To optimize effectiveness of this product in the control of haemonchosis in a flock, a sustainable integrated pest management program should be instituted at the farm level. Flukiver can be used in rams and ewes at any time, including during the breeding season. Flukiver should not be used in ewes producing milk for human consumption (see WARNINGS).

Contraindications:

Do not exceed the stated dose.
Do not repeat administration at less than 49 day intervals.

Cautions:

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
• Too frequent and repeated use of this anthelmintic, or other anthelmintics from the same class, over an extended period of time.
• Administration of a subtherapeutic dose, either intentionally or inadvertently, through underestimating the weight of the individual animal, failure to administer the product correctly or inaccurate calibration of the dosing device.
Suspected cases of anthelmintic resistance, e.g. failure of resolution of haemonchosis after treatment, should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
To reduce the risk of anthelmintic resistance, dosing programs should be discussed with a veterinarian.
When using a drenching gun, take care not to injure the mouth or pharynx.

Warnings:

Treated sheep must not be slaughtered for use in food for at least 49 days after the latest treatment with this drug.
Do not use in lactating ewes producing milk for human consumption.
Do not use in dairy ewes during pregnancy, including dry period. The safety of residues in milk during subsequent lactation has not been established.
Avoid contact with skin and eyes. Avoid inhalation of vapours. Wash hands after handling.

Keep out of reach of children.

Adverse Reactions:

Adverse events that have been reported have been associated with overdose of the product. Clinical signs of acute overdosage are decreased vision, blindness, anorexia, incoordination and general weakness.

Pharmacodynamics:

Flukiver oral suspension contains the salicylanilide closantel, a synthetic antiparasitic agent with high efficacy against haematophagous nematodes in sheep. Closantel uncouples the mitochondrial oxidative phosphorylation resulting in inhibition of ATP synthesis. This induces a marked change in the energy metabolism of the parasite which finally kills it.

Pharmacokinetics:

Closantel is rapidly absorbed into the systemic circulation with peak plasma levels at 24-48 hours after dosing. The bioavailability of an oral dose is 50% of a parenteral one. In plasma, closantel is 99% bound to albumin. As a result, tissue distribution is very limited. On average, tissue levels are 15 times lower than plasma levels. The elimination half-life of closantel from plasma and tissues is approximately 2 to 4 weeks in sheep. Closantel is metabolized only to a slight extent and the main excretion route is the bile. The urinary excretion is negligible.

Efficacy:

A clinical field trial performed in Canada on six commercial sheep farms employing pasture for grazing ewes and lambs demonstrated the efficacy of closantel against *Haemonchus* sp. as both a whole flock treatment as well as part of a targeted selective treatment program. Targeted selective treatment was based on nursing lamb numbers per ewe, body condition scoring, previous grazing history and mucous membrane evaluation for signs of anemia. The frequency of treatments was no different between the whole flock treatment and selectively treated farms, while closantel use was reduced up to 51% in the three selectively treated farms without a significant difference in clinical haemonchosis or losses due to GI parasitism compared with the three whole flock treatment farms.

Safety:

Clinical signs of toxicity reported in multiple tolerance and toxicity studies were dilated pupils, recumbency, general weakness, anorexia, laboured breathing, depression and drowsy appearance. These clinical signs were observed starting at doses of 50 mg/kg.

Storage:

Do not store above 30°C.

Protect from light.

Once opened the product should be stored for a maximum of 3 months. Discard unused portion.

How supplied:

Flukiver is available in 2.5 litre flexipack/bottles.

Disposal:

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

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