SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 50 mg/ml Oral Suspension for sheep and lambs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

50 mg closantel (as closantel sodium)
Excipients:

Qualitative composition of excipients and other constituents
Propylene Glycol
Microcrystalline Cellulose and Carmellose Sodium
Hypromellose
Sodium Lauryl Sulphate
Simethicone Emulsion
Water purified

Off-white to slightly yellow, homogeneous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and lambs.

3.2 Indications for use for each target species

For the control of chronic and subacute fascioliasis (due to *Fasciola hepatica*) in sheep and lambs.
For the control of *Oestrus ovis* (Sheep Nasal Bot Fly).
For the control of inhibited, immature and adult stages of *Haemonchus contortus* (Barber Pole Worm) including benzimidazole resistant strains.

The veterinary medicinal product is active against mature and immature flukes.

Fluke activity:

Stage	*Percentage kill*
Adults	97-100 %
6-8 weeks immature	91-95%
5 weeks immature	91%
3-4 weeks immature	23-73 %

Ticks (*Ixodes ricinus*) feeding on sheep at the time of treatment are likely to produce fewer viable eggs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 anthelmintics from the same class, over an extended period of time.
Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics 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. Resistance to closantel has been reported in *Haemonchus* outside the EU. The use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When using a drenching gun, take care not to injure the mouth or pharynx.
Do not exceed the stated dose.

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

Wash hands after administration.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 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

The veterinary medicinal product can be used in all age groups of sheep and lambs.
Fertility:
Can be used in rams at any time, including during the breeding season.
Pregnancy:
Can be used at any time during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No interactions have been observed.

3.9 Administration routes and dosage

For oral administration as a drench.
Suitable for use with most types of standard drenching equipment.

1 ml of the veterinary medicinal product per 5 kg bodyweight (ie 10 mg closantel per kg bodyweight).

For example:

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

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Shake well before use.
Do not mix with other products.

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

Symptoms of acute overdosage are decreased vision or blindness, anorexia, in-coordination and general weakness.

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

Meat and offal: 56 days
Not authorised for use in ewes producing milk for human consumption, including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AG09

4.2 Pharmacodynamics

Flukiver Oral Suspension contains the salicylanilide closantel, a synthetic antiparasitic agent with high efficacy against liver fluke and haematophagous nematodes in sheep and goats and against the larval stages of some arthropods 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.

4.3 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 bound to albumin for more than 99 %. 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 and about 8 days in goats. Closantel is metabolised only to a slight extent and the main excretion route is the bile. The urinary excretion is negligible.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

Do not store above 25 °C.

Keep the container in the outer carton in order to protect from light.

The time between withdrawal of the first and last doses from the container should not be unduly prolonged.

5.4 Nature and composition of immediate packaging

1, 2.5 and 5 litres high density polyethylene flexipack/bottle with tamper evident high density polyethylene cap (screw-fit).

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.

The veterinary medicinal product should not enter water courses as closantel may be dangerous for fish and other aquatic organisms.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5066

8. DATE OF FIRST AUTHORISATION

01 December 1986

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

October 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.

Approved 28 January 2026

Gavin Hall