SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 5% w/v Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	**mg/ml**
Closantel	50.00
(as Closantel Sodium Dihydrate	54.375)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
Off-white to slightly yellow, homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and lambs

4.2 Indications for use, specifying the 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.

Flukiver 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.

4.3 Contraindications

None

4.4 Special warnings for target species

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* in 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.

4.5 Special precautions for use

i. Special precautions for use in animals

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

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

Wash hands after administration.

4.6 Adverse reactions (frequency and seriousness)

None known. Flukiver can be used in all age groups of sheep and lambs. It can also be used in rams at any time including during the breeding season.

4.7 Use during pregnancy, lactation or lay

Flukiver can be used at any time during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions have been observed.

4.9 Amounts to be administered and administration route

1 ml of Flukiver 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 administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Give orally as a drench. Suitable for use with most types of standard drenching equipment.
Shake well before use.
Do not mix with other products.

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

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

4.11 Withdrawal period(s)

Meat: 42 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Vet Code: QP52AG09

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Microcrystalline Cellulose and Carmellose Sodium
Hypromellose
Sodium Lauryl Sulphate
Simethicone Emulsion
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not store above 25 °C.
Protect from light.

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

6.5 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.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eli Lilly and Company Limited
Elanco Animal Health
Lilly House
Priestley Road
Basingstoke
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00006/4142

9. DATE OF FIRST AUTHORISATION

Date: 01 December 1986

10 DATE OF REVISION OF THE TEXT

Date: February 2013

Aprroved:
08/03/13