Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 5% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Closantel (as Clostanel sodium) 50 mg/ml

Excipients:

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.
A white suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and lambs.

4.2 Indications for use, specifying the target species

For the treatment and control of adult and immature liver fluke, haematophagous nematodes and larval stages of some arthropods in sheep.

Liver fluke:

Fasciola hepatica (average efficacy against 6 week immature stages is 86%)
Fasciola gigantica

Haematophagous nematodes

Haemonchus contortus (including benzimidazole resistant strains)
Chabertia ovina
Gaigeria pachyscelis

Arthropods

Oestrus ovis (Sheep Nasal Bot Fly)
Ticks (*lxodes ricinus*) feeding on sheep at the time of treatment are likely to produce fewer viable eggs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each 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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals:

Do not overdose. Care should be taken when administering the product to avoid causing injury to the pharynx. Appropriate drenching equipment to allow accurate dosing should be used.

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)

At therapeutic doses Flukiver is not toxic and causes no side effects.

4.7 Use during pregnancy, lactation or lay

Flukiver can be used at any time during pregnancy and during the lactating period. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
Shake well before use.
1 ml of Flukiver per 5 kg bodyweight (i.e. 10 mg closantel per kg bodyweight).
Bodyweight of animals should be assessed accurately.

For example:

BodyweightDose
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

Fluke infestations

All sheep on infested pasture should be dosed at regular intervals during the fluke season (September - March).

Since closantel has been shown to delay egg laying for up to 13 weeks after artificial infection, treatment intervals of 10-12 weeks throughout the fluke season are recommended. In severe fluke seasons more frequent dosing may be necessary. The treatment of ewes with a single dose of Flukiver in the spring will contribute to reducing pasture contamination during the following summer and autumn.

Any sheep brought in from liver fluke infested areas should be dosed before they join the flock.

H. contortus

For the treatment and prevention of benzimidazole resistant and susceptible *H. contortus*, dose at lambing to help prevent pasture contamination by infected ewes. Treat all animals at 6 weekly intervals during high risk periods in summer and autumn.
The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

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

Symptoms of acute overdosage include decreased vision or blindness, anorexia, inco-ordination 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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, closantel.
ATCvet code: QP52AG09

5.1 Pharmacodynamic properties

Flukiver 5% 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 faeces via the bile. The urinary excretion is negligible.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Microcrystalline Cellulose and Carmellose sodium
Hypromellose 15 cps
Sodium Laurilsulfate
Simethicone emulsion 30 %
Purified water

6.2 Major 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^{o}C.Protect from light

6.5 Nature and composition of immediate packaging

The product is packed in white high density polyethylene flexipacks containing 1 litre, 2.5 litres and 5 litres of product.

Closures: Tamper evident high density polyethylene cap (screw-fit) with high density polyethylene screw fit nozzle cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

June 2018