Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 50 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Closantel (as Closantel sodium) 50 mg/ml

Excipients

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Trematodes
Fasciola hepatica
Fasciola gigantica

Nematodes
Haemonchus placei
Bunostomum phlebotomum
Oesophagostomum radiatum

Arthropods
Hypoderma bovis
Hypoderma lineatum

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not exceed the stated dose.
Care should be taken to ensure that all injection procedures are correctly carried out and body weights accurately assessed.

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.

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.

4.5 Special precautions for use

Special precautions for use in animals
None

Special precautions to be taken by the person administering the veterinay medicinal product to animals
Wash hands after administration. Take care to avoid accidental self-administration.

4.6 Adverse reactions (frequency and seriousness)

The solution contains polyvidone. This substance may in very exceptional cases induce hyperacute anaphylactic reactions in cattle.

4.7 Use during pregnancy, lactation or lay

Flukiver 50 mg/ml Solution for Injection is safe for use during pregnancy and lactation. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

2.5 mg/kg sc (1 ml/20 kg BW)	**Adults**	**Immatures**
Fasciola hepatica	X	
Fasciola gigantica	X	
Haemonchus placei	X	X
Bunostomum phlebotomum	X	
Oesophagostomum radiatum	X	

5 mg/kg sc (1 ml/10 kg BW)	**Adults**	**Immatures**
Fasciola hepatica	X	6 weeks*
Fasciola gigantica	X	8 weeks*
Haemonchus placei	X	X
Bunostomum phlebotomum	X	X
Oesophagostomum radiatum	X	X
Hypoderma bovis	Dermal stages	
Hypoderma lineatum	Dermal stages	

*average efficacy against 6 week immature stages of *Fasciola hepatica* is 73% in cattle.
Because of its long half-life, closantel will protect for several weeks against re-infections with the following nematodes:

Residual Activity	**Dose (mg/kg)**	**Protection Period**
Haemonchus placei	2.5	4 weeks
	5	6 weeks
Bunostomum phlebotom	5	3 weeks
Oesophagostomum radiatum	5	2 weeks

Method of administration
Flukiver 50 mg/ml Solution for Injection is to be given by the subcutaneous route. Inject cattle under the loose skin of the neck.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
When large volumes have to be injected (more than 20 ml), divide the total volume equally over both neck sizes.

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

Symptoms of acute overdosage are decreased vision or blindness, anorexia, incoordination and general weakness.

4.11 Withdrawal period(s)

A period of 77 days should be observed between the last administration of the drug and the time of slaughtering of animals for human consumption.
Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, phenol derivatives, including salicylanilides
ATCvet Code: QP52AG09

5.1 Pharmacodynamic properties

Flukiver 50 mg/ml Solution for Injection contains the salicylanilide closantel, a synthetic antiparasitic agent with high efficacy against liver fluke, haematophagous nematodesand larval stages of some arthropods in cattle.

Closantel is an uncoupler of mitochondrial oxidative phosphorylation resulting in inhibition of ATP synthesis. This induces a marked change in the energymetabolism and finally leads to death of the parasite.

5.2 Pharmacokinetic particulars

Closantel is rapidly absorbed into the systemic circulation with peak plasma levels at 24-48 hours after dosing. In plasma, closantel is bound 99% 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 9 to 21 days in cattle. The drug is poorly metabolised and the main excretion route is in the faeces via the bile. Urinary excretion in negligible.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Povidone
Citric Acid Monohydrate
Sodium Hydroxide
Citric Acid Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Container or pack size: 1 or 4 amber Type I glass vials.
Closure: Grey bromobutyl siliconised rubber stopper.

Cap: Aluminium cap with silver aluminium flip-off lid
Contents of each vial: 250 ml aqueous solution.
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 materials should be disposed of in accordance with national requirements.
Flukiver 50 mg/ml Solution for Injection should not enter water courses as this may be dangerous to fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

November 2020