1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 50 mg/ml Solution for Injection

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
Povidone
Citric Acid Monohydrate
Sodium Hydroxide
Citric Acid Water for Injections

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For treatment of adult and immature liver flukes and haematophagous nematodes in cattle.

Trematodes
Fasciola hepatica
Fasciola gigantica

Nematodes
Haemonchus placei
Bunostomum phlebotomum
Oesophagostomum radiatum

Arthropods
Hypoderma bovis
Hypoderma lineatum

3.3 Contraindications

None.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None

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

Special precautions for the protection of the environment:
See also section 5.5.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[1]

[1]This solution contains polyvidone and may induce this reaction in cattle.

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

Pregnancy and lactation:

The veterinary medicinal product is safe for use during pregnancy and lactation. See section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 Hypoderma lineatum	Dermal stages 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
The veterinary medicinal product 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.

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

Symptoms of acute overdosage are decreased vision or blindness, anorexia, incoordination 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: 77 days.
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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AG09

4.2 Pharmacodynamics

The veterinary medicinal product 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.

4.3 Pharmacokinetics

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 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: 36 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Container or pack size: 1 or 4 amber 250 ml Type I glass vials.
Closure: Grey bromobutyl siliconised rubber stopper.
Cap: Aluminium cap with silver aluminium flip-off lid.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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(S)

VPA22020/002/001

8. DATE OF FIRST AUTHORISATION

01 October 1989

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

10 December 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).