# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUKIVER BOVIS 50 mg/ml Solution for Injection for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**

| | | |
|---|---|---|
| Closantel | 50 | mg |
| (equivalent to closantel sodium dihydrate | 54.375 | mg) |

**Excipients:**

| | | |
|---|---|---|
| Propylene glycol | 414.4 | mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow to amber solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle

### 4.2 Indications for use, specifying the target species

For the treatment and control of liver fluke, gastro-intestinal nematodes and arthropods.

**Trematodes**
- *Fasciola hepatica*
- *Fasciola gigantica*

**Nematodes**
- *Haemonchus placei*
- *Bunostomum phlebotomum*
- *Oesophagostomum radiatum*

**Arthropods**
- *Hypoderma bovis*
- *Hypoderma lineatum*

### 4.3 Contraindications

See section 4.11.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Not for IV or IM use.

## 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.
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.
To reduce the risk of anthelmintic resistance, veterinary advice should be sought when establishing dosing programmes.

## 4.5 Special precautions for use

### i) Special precautions for use in animals

None

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

In case of accidental self-administration seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

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

## 4.7 Use during pregnancy, lactation or lay

Flukiver Bovis 50 mg/ml Solution for Injection may be administered to pregnant animals. The product may be used during the lactation period but should not be administered to animals producing milk for human consumption. 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 routine treatment on farms: 2.5 mg/kg sc (1 ml/20 kg BW):**

| 2.5 mg/kg sc (1 ml/20 kg | Adults |
|---|---|
| *Fasciola hepatica* | X |
| *Fasciola gigantica* | X |
| *Haemonchus placei* | X |
| *Bunostomum* | X |
| *Oesophagostomum* | X |

**For treatment of severe infections: 5 mg/kg sc (1 ml/10 kg BW):**

| 5 mg/kg sc (1 ml/10 kg | Adults | Immature |
|---|---|---|
| *Fasciola hepatica* | X | 8 weeks |
| *Fasciola gigantica* | X | 8 weeks |
| *Haemonchus placei* | X | X |
| *Bunostomum* | X | X |
| *Oesophagostomum* | X | X |
| *Hypoderma bovis* | Dermal stages | |
| *Hypoderma lineatum* | Dermal stages | |

Because of its long half-life, closantel will protect for several weeks against re-infections with the following nematodes:

| Residual Activity | Dose | Protection |
|---|---|---|
| *Haemonchus placei* | 2.5 | 4 weeks |
| | 5 | 6 weeks |
| *Bunostomum* | 5 | |
| *Oesophagostomum* | 5 | 2 weeks |

**Method of administration**

Flukiver Bovis 50 mg/ml Solution for Injection is to be given by the subcutaneous route. Inject cattle under the loose skin of the neck.
When large volumes have to be injected (more than 20 ml), divide the total volume equally over both neck sides.

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

If treatment is to be repeated, a minimum of 11 week interval must be observed in order to avoid accumulation of residues.

### 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 and offal: 77 days
Milk: 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 PROPERTIES

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

### 5.1 Pharmacodynamic properties

Flukiver Bovis 50 mg/ml Solution for Injection contains the salicylanilide closantel, a synthetic antiparasitic agent with high efficacy against liver fluke, haematophagous nematodes and 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 energy metabolism 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 is negligible.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Propylene glycol
Povidone
Citric acid monohydrate (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

### 6.2 Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

## 6.4 Special precautions for storage

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

## 6.5 Nature and composition of immediate packaging

Container & Pack size: 250 ml amber Type I glass vials
Presentation: 1 x 250 ml or 4 x 250 ml
Closure: Grey bromobutyl siliconised rubber stopper
Cap: Red coloured aluminium
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 product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Flukiver Bovis 50 mg/ml Solution for Injection should not enter water courses as this may be dangerous for fish and other aquatic organisms.

# 7. MARKETING AUTHORISATION HOLDER

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

# 8. MARKETING AUTHORISATION NUMBER

Vm 00006/4153

# 9. DATE OF FIRST AUTHORISATION

02 August 2010

# 10. DATE OF REVISION OF THE TEXT

October 2015

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