FLUKIVER® BOVIS 50 mg/ml Solution for Injection for Cattle

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUKIVER® BOVIS 50 mg/ml Solution for Injection for cattle
Closantel
(Tradename may be different from country to country)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

- Closantel 50 mg (equivalent to 54.375 mg closantel sodium dihydrate) as active
- 414.4 mg propylene glycol as excipient

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

4 x 250 ml
1 x 250ml

5. TARGET SPECIES

Cattle
<Pictogram of cattle>

6. INDICATION(S)

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

7. METHOD AND ROUTE (S) OF ADMINISTRATION

Directions for use: For subcutaneous use only
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
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.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid introduction of contamination during use.

10. EXPIRY DATE

Expiry: <MM-YYYY>

Once broached, use the product within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not allow to enter watercourse.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

To be completed locally

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed locally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed locally

17. MANUFACTURER'S BATCH NUMBER

Batch No:

18. ADDITIONAL INFORMATION

To be completed locally

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUKIVER® BOVIS 50 mg/ml Solution for Injection for cattle
Closantel
(Tradename may be different from country to country)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

- Closantel 50 mg (equivalent to 54.375 mg closantel sodium dihydrate) as active
- 414.4 mg propylene glycol as excipient

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle
<Pictogram of cattle>

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route of administration: subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
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.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid introduction of contamination during use.

10. EXPIRY DATE

Expiry: <MM-YYYY>

Once broached, use the product within 28 days.
Once broached, use by: …

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be completed locally

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed locally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed locally

17. MANUFACTURER'S BATCH NUMBER

Batch No:

18. ADDITIONAL INFORMATION

To be completed locally

B. PACKAGE LEAFLET

PACKAGE LEAFLET

FLUKIVER® BOVIS 50 mg/ml Solution for Injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
To be completed locally

Manufacturer responsible for the batch release:
Sanochemia Pharmazeutika AG
Landegger Strasse 7
A-2491 Neufeld/Leitha
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUKIVER® BOVIS 50 mg/ml Solution for Injection for cattle
Closantel
(Tradename may be different from country to country)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of clear yellow amber solution contains:
- Closantel 50 mg (equivalent to 54.375 mg closantel sodium dihydrate) as active
- 414.4 mg propylene glycol as excipient

4. INDICATION(S)

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*

5. CONTRAINDICATIONS

See section 10.

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

Not for IV or IM. use.

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle
For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Method of administration
Flukiver Bovis 50 mg/ml Solution for Injection is to be given by the subcutaneous route.

Dosage
For routine treatment on farms: 2.5 mg/kg sc (1 ml/20 kg BW):

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

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

5 mg/kg sc (1 ml/10 kg BW)	Adults	Immatures
Fasciola hepatica	X	8 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	

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 phlebotomum	5	
Oesophagostomum radiatum	5	2 weeks

9. ADVICE ON CORRECT 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.

10. WITHDRAWAL PERIOD

Withdrawal period:
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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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.

Special precautions for use in animals
None.

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

Use during pregnancy or lactation
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 10.

Interaction with other medicinal products and other forms of interaction
None known.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Symptoms of acute overdosage are decreased vision or blindness, anorexia, in-coordination and general weakness.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed locally

15. OTHER INFORMATION

Pack sizes:
1 x 250 ml glass vials and 4 x 250 ml glass vials.

Not all pack sizes may be marketed.

To be completed locally