A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Santiola 50 mg/ml solution for injection for cattle and sheep (BG, CZ, EE, GB, HR, HU, IE, LT, LV, RO, SI, SK)
Santiola vet 50 mg/ml solution for injection for cattle and sheep (DK, SE)
Closantel

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains

Active substance:
Closantel 50 mg
(equivalent to closantel sodium dihydrate 54.375 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 250 ml
4 x 250 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For OTC products
For treatment of fluke, gastro-intestinal worms and arthropods (larval stages of bot flies in sheep and warble flies in cattle) if sensitive to closantel.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle: meat and offal: 77 days
Sheep: meat and offal: 107 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.
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days
Once broached use by...

11. SPECIAL STORAGE CONDITIONS

Store below 30 °C.
Store in the original container in order to protect from light.
Once opened, store below 25 °C.

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

Disposal: read package leaflet.

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

For animal treatment only.

For Rx products: To be supplied only on veterinary prescription.

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

KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4118

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Santiola 50 mg/ml solution for injection for cattle and sheep (BG, CZ, EE, GB, HR, HU, IE, LT, LV, RO, SI, SK)
Santiola vet 50 mg/ml solution for injection for cattle and sheep (DK, SE)
Closantel

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains

Active substance:
Closantel 50 mg
(equivalent to closantel sodium dihydrate 54.375 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For OTC products
For treatment of fluke, gastro-intestinal worms and arthropods (larval stages of bot flies in sheep and warble flies in cattle) if sensitive to closantel.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle: meat and offal: 77 days
Sheep: meat and offal: 107 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.
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 28 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Store below 30 °C.
Store in the original container in order to protect from light.
Once opened, store below 25 °C.

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

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

For animal treatment only.

For Rx products: To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4118

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Santiola 50 mg/ml solution for injection for cattle and sheep (BG, CZ, EE, GB, HR, HU, IE, LT, LV, RO, SI, SK)
Santiola vet 50 mg/ml solution for injection for cattle and sheep (DK, SE)

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

Marketing authorisation holder:
KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Santiola 50 mg/ml solution for injection for cattle and sheep (BG, CZ, EE, GB, HR, HU, IE, LT, LV, RO, SI, SK)
Santiola vet 50 mg/ml solution for injection for cattle and sheep (DK, SE)
Closantel

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

1 ml contains

Active substance:
Closantel 50 mg
(equivalent to closantel sodium dihydrate 54.375 mg)

Clear light yellow to yellow or brown yellow solution.

4. INDICATION(S)

For treatment of the following trematodes (fluke), gastro-intestinal nematodes and arthropods if sensitive to closantel.

Sheep

Flukes (trematodes)
Liver fluke – *Fasciola hepatica* (adult)
Giant liver fluke – *Fasciola gigantica* (adult and 8 weeks immature)

Gastro-intestinal worms (nematodes)
Stomach worm – *Haemonchus contortus* (adult and immature)
Nodule worm – *Oesophagostomum columbianum* (adult and immature)
Hookworm *Gaigeria pachyscelis* (adult and immature)
Large-mouthed bowel worm – *Chabertia ovina* (adult and immature)

Bot flies (arthropods)
Sheep nasal fly – *Oestrus ovis* (1st, 2 nd and 3rd instar)

Cattle

Flukes (trematodes)
Liver fluke – *Fasciola hepatica (adult)*
Giant liver fluke – *Fasciola gigantica (adult and 8 weeks immature)*

Gastro-intestinal worms (nematodes)
Barber's pole worm – *Haemonchus placei* (adult and immature)
Cattle hookworm – *Bunostomum phlebotomum* (adult and immature)
Nodular worm – *Oesophagostomum radiatum* (adult and immature)

Warble flies (arthropods)
Hypoderma bovis (dermal stages)
Hypoderma lineatum (dermal stages)

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

The solution contains polyvidone. This substance may in very rare cases induce hyperacute anaphylactic reactions (an immediate and serious allergic reaction, which may cause difficulty in breathing, restlessness and excitement, and other general and local changes at the site of injection) in cattle.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and sheep

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

Route of administration:
Cattle: subcutaneous route
Sheep: subcutaneous route

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Dose:
Cattle

<table>
<tr><th>Parasite</th><th>Adults</th><th>Immatures</th></tr>
<tr><td>Liver fluke – Fasciola hepatica</td><td rowspan="5">2.5 mg/kg BW (1 ml/20 kg)
or
5 mg/kg BW (1 ml/10 kg)</td><td>/</td></tr>
<tr><td>Giant liver fluke – Fasciola gigantica</td><td>From 8 weeks after infection:
5 mg/kg BW (1 ml/10 kg)</td></tr>
<tr><td>Barber’s pole worm – Haemonchus placei</td><td>2.5 mg/kg BW (1 ml/20 kg)
or
5 mg/kg BW (1 ml/10 kg)</td></tr>
<tr><td>Cattle hookworm – Bunostomum phlebotomum</td><td>5 mg/kg BW (1 ml/10 kg)</td></tr>
<tr><td>Nodular worm – Oesophagostomum radiatum</td><td>5 mg/kg BW (1 ml/10 kg)</td></tr>
<tr><td>Warble flies – Hypoderma spp.</td><td colspan="2">Dermal stages: 5 mg/kg BW (1 ml/10 kg)</td></tr>
</table>

Sheep

Parasite	**Adults**	**Immatures**
Liver fluke – *Fasciola hepatica*	5 mg/kg BW (1 ml/10 kg)	/
Giant liver fluke – *Fasciola gigantica*		From 8 weeks after infection: 5 mg/kg BW (1 ml/10 kg)
Hookworm *Gaigeria pachyscelis*	2.5 mg/kg BW (1 ml/20 kg)	2.5 mg/kg BW (1 ml/20 kg)
Stomach worm – *Haemonchus contortus*	2.5 mg/kg BW (1 ml/20 kg) or 5 mg/kg BW (1 ml/10 kg)	2.5 mg/kg BW (1 ml/20 kg) or 5 mg/kg BW (1 ml/10 kg)
Stomach worm – *Haemonchus contortus* (benzimidazole-resistant strains)	5 mg/kg BW (1 ml/10 kg)	5 mg/kg BW (1 ml/10 kg)
Nodule worm – *Oesophagostomum columbianum*		
Large-mouthed bowel worm – *Chabertia ovina*		
Sheep nasal fly – *Oestrus ovis*	1., 2. and 3. instar: 2.5 mg/kg BW (1 ml/20 kg)	

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

Cattle

Residual Activity	Dose (mg/kg BW)	Protection Period
Barber's pole worm – *Haemonchus placei*	2.5	4 weeks
	5	6 weeks
Cattle hookworm – *Bunostomum phlebotomum*	5	3 weeks
Nodular worm – *Oesophagostomum radiatum*	5	2 weeks

Sheep

Residual Activity	Dose (mg/kg BW)	Protection Period
Stomach worm – *Haemonchus contortus*	2.5	2 weeks
	5	7 weeks
Hookworm *Gaigeria pachyscelis*	2.5	3 weeks
	5	8 weeks
Sheep nasal fly – *Oestrus ovis*	5	8 weeks

9. ADVICE ON CORRECT ADMINISTRATION

When large volumes have to be injected (more than 20 ml), divide the total volume equally over both neck sides.
Do not exceed 20 broachings per vial. If more than 20 broachings are required, use of a draw off needle is recommended.
If treatment is to be repeated, a minimum interval of 11 weeks for cattle and 107 days for sheep must be observed in order to avoid accumulation of residues.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: 77 days
Sheep: meat and offal: 107 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.
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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30 °C.
Store in the original container in order to protect from light.
Once opened, store below 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the container 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 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.

Special precautions for use in animals
Safe and efficacious use of this product at a dose of 2.5 mg/kg is dependent on accurate species level parasitological diagnosis of risks at farm level. Where this is unavailable, the dose rate of 5 mg/kg must be used.
Closantel is toxic to dung fauna.
To reduce the risk for the dung fauna, treated and untreated animals should be grazed on the same field.
In order to reduce the risk to aquatic organisms, treated animals should be kept out of water for at least 48 hours after treatment.

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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.
See section 10. Withdrawal Period.

Interaction with other medicinal products and other forms of interaction, and incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):
Symptoms of acute overdosage are decreased vision or blindness, anorexia, incoordination and general weakness.

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.
The product 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

July 2019

15. OTHER INFORMATION

Container or pack size: 1 or 4 type I amber glass vials.
Closure: bromobutyl rubber.
Contents of each vial: 250 ml solution.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Vm 01656/4118

Approved: 08 August 2019