SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solantel 200mg/ml Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains:

Active substance:

Closantel	200 mg
(as Closantel Sodium Dihydrate	217.5 mg)

Excipients:

Brilliant Blue FCF (E133)	0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-On solution.
A clear blue/green solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For the treatment of late immature (≥ 7 weeks) and adult *Fasciola hepatica* (fluke) infestations of cattle.

4.3 Contraindications

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

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

4.4 Special warnings for each 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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

The effect of rain on the pour-on formulation at the time of and after application has not been investigated. For maximum effect animals should be kept indoors or undercover following treatment, when there is rain or an imminent risk of rain.

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 tests 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

Care should be taken to ensure animals are not overdosed by the application volume, accidental spillage or oral ingestion, as overdosage may result in signs of toxicity such as inco-ordination and blindness. It is recommended that animals are not clipped prior to treatment to reduce the risk of increased drug absorption and hence bioavailability, or oral ingestion through mutual grooming.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations (see section 4.11) or in very rare cases, it can lead to adverse events (see section 4.6) in non-treated animals.

Care should be taken when treating animals which may be of low nutritional status as this may increase susceptibility of adverse events occurring.

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

This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause irritation to human skin and eyes.
This product may cause hypersensitivity (allergic) reactions in those known to be sensitised to polyethylene glycols (PEGs), povidones, isopropyl alcohol, triethanolamine, ethanol, and/or closantel.
Do not use in cases of known hypersensitivity to the active substance or to any of these excipients.
Avoid skin or eye contact with product.
Users should wear nitrile rubber gloves and boots with a waterproof coat when applying the product.
If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention. Wash any exposed skin after use. Protective clothing should be washed after use.

This product is flammable.

Keep away from heat, sparks, open flame or other sources of ignition.
Store in a closed cabinet. Do not smoke or eat while handling the product.

This product contains volatile organic solvents, which may be accidentally inhaled.
Use only in well ventilated areas or outdoors.

Other precautions:

This product is very toxic to aquatic organisms and dung insects.
Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, neurological signs such as blindness, ataxia and recumbency may occur after administration of the product. These cases may also be associated with gastrointestinal signs such as anorexia, diarrhoea and in extreme cases signs may persist and may result in death of the animal. Even though the overall incidence of adverse events is very rare, it has been noted that, when there is an adverse event in a herd, several animals may be affected. Therefore, should neurological signs be observed in one animal, it is recommended to reinforce surveillance, at the herd level, of all treated animals.

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).

4.7 Use during pregnancy, lactation or lay

The product can be administered to cattle (including dairy, beef/suckler cattle) at any stage of pregnancy or lactation provided that the milk is not intended 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

Single administration only.

The veterinary medicinal product should be administered topically at a dosage rate of 20 mg closantel per kg bodyweight (1 mL per 10 kg).

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tail head.

Assess bodyweight carefully prior to administration.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. The product should not be repeatedly applied to cattle within 10 weeks of first administration.

Handy Dosing Guide		**Animals should be weighed and grouped according to bodyweight to avoid under or over-dosing**		
Bodyweight	**Dose Volume**	**Number of Full Doses per Pack**		
		1 Litre	**2.5 Litre**	**5 Litre**
100 kg*	10 ml	100	250	500
150 kg	15 ml	66	166	333
200 kg	20 ml	50	125	250
250 kg	25 ml	40	100	200
300 kg	30 ml	33	83	166
350 kg	35 ml	28	71	142
400 kg	40 ml	25	62	125
450 kg	45 ml	22	55	111
500 kg	50 ml	20	50	100
550 kg	55 ml	18	45	90
600 kg	60 ml	16	41	83

* Dose rate 1 ml per 10 kg bodyweight

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

At doses of three times the recommended dose, no significant clinical signs were recorded.

Closantel like other salicylanilides is a potent uncoupler of oxidative phosphorylation and the safety index is not as high as is the case of many other anthelmintics. Signs of overdosage can include slight loss of appetite, loose faeces, decreased vision and increased frequency of defecation. High doses may cause blindness, hyperventilation, general weakness and inco-ordination, hyperthermia, convulsions, tachycardia and in extreme cases death. Treatment of overdosage is symptomatic as no antidote has been identified.

4.11 Withdrawal period(s)

Cattle (meat and offal): 63 days.

Not authorised for use in cattle producing milk for human consumption, including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

Because of the potential for cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residue violations in non-treated animals.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anthelmintics, phenol derivatives, including salicylanilides.
ATC Vet Code: QP52AG09

5.1 Pharmacodynamic properties

Closantel is a member of the salicylanilide class of anthelmintics. Salicylanilides are hydrogen (proton) ionophores (referred to as oxidative phosphorylase uncouplers.)

The chemical structure of salicylanilides illustrate the possession of a detachable proton. This type of molecule is lipophilic and is known to shuttle protons across membranes, in particular the inner mitochondrial membrane. Closantel acts by uncoupling oxidative phosphorylation.

Closantel is a parasiticide with activity against fluke.

5.2 Pharmacokinetic particulars

After topical administration of the product to cattle at a dose rate of 20 mg closantel per kg the following parameters were observed: Closantel – Cmax of 57 (SD ± 52) µg/mL, AUC of 34690 (SD ± 29922) µg/hr/mL, Tmax of 223 (SD ± 327) hours (median value) and t½ of 385 (SD ± 95) hours (harmonic mean).

Salicylanilides are poorly metabolised and are excreted mainly unchanged. About 90% of closantel is excreted unchanged in the faeces and urine in cattle.

Environmental properties

See sections 4.5 and 6.6.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant Blue FCF (E133) Dye
Ethanol, anhydrous
Macrogol
Cetearyl ethylhexanoate
Isopropyl myristate
Povidone
Denatonium benzoate
Trolamine
Isopropyl alcohol

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 16 months.
Shelf life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Do not store above 25°C.
Store upright in original container in order to protect from light.
If stored at temperatures below 0°C, the product may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Flammable – keep away from heat, sparks, open flame or other sources of ignition.

6.5 Nature and composition of immediate packaging

White 1L, 2.5L and 5L HDPE backpacks for use with a suitable dosing device and white polypropylene screw caps.

Not all packs 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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co Down
BT35 6JP

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4442

9. DATE OF FIRST AUTHORISATION

16 June 2021

10 DATE OF REVISION OF THE TEXT

July 2024

Gavin Hall

Approved: 20 December 2024