Solantel 200mg/ml Pour-On Solution for Cattle

Presentation:

Solantel 200mg/ml Pour-On Solution for Cattle is a clear blue/green Pour On Solution. Each 1 ml dose contains Closantel 200 mg (as Closantel Sodium Dihydrate 217.5 mg).

Uses:

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

Dosage and administration:

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. Single administration only. 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 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

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. 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.

Withdrawal period:

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.

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Contraindications and Warnings:

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.

In very rare cases rare (less than 1 animal in 10,000 animals treated, including isolated reports), 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.

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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 incoordination 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.

Operator warnings:
This product may be toxic after accidental ingestion. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Users should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Avoid skin or eye contact with product. Do not use in cases of known hypersensitivity to polyethylene glycols, povidones, isopropyl alcohol, triethanolamine, ethanol, and/or closantel.
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.

Pharmaceutical precautions:
Shelf life of the veterinary medicinal product as packaged for sale: 16 months.
Shelf life after first opening the immediate packaging: 6 months.
Do not store above 25°C. Store upright in original container in order to protect from light.

Legal category: UK POM-VPS; ROI POM.

Package quantity:
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.

Disposal:
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.

Marketing Authorisation numbers:
UK: Vm02000/4442
ROI: VPA22664/150/001

Manufactured and distributed in NI by:
Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co Down, BT35 6JP.

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Distributed in ROI by:
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KEEP OUT OF SIGHT AND REACH OF CHILDREN.
FOR ANIMAL TREATMENT ONLY.