ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1L, 2.5L, 5L HDPE Backpacks}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solantel 200mg/ml Pour-On Solution for Cattle
Closantel (as Closantel Sodium Dihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains:

Closantel	200 mg
(as Closantel Sodium Dihydrate	217.5 mg)
Brilliant Blue FCF (E133)	0.1 mg

3. PHARMACEUTICAL FORM

Pour-On solution.

4. PACKAGE SIZE

1L, 2.5L, 5L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 1ml per 10kg bodyweight

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {dd/mm/yyyy}
Shelf life after first opening the immediate packaging: 6 months.
Once opened use within 6 months, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store upright in original container in order to protect from light.
See package leaflet for full storage conditions.

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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4442

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{1L, 2.5L, 5L HDPE Backpacks}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solantel 200mg/ml Pour On Solution for Cattle
Closantel (as Closantel Sodium Dihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

1ml of solution contains:

Closantel	200 mg
(as Closantel Sodium Dihydrate	217.5 mg)
Brilliant Blue FCF (E133)	0.1 mg

3. PHARMACEUTICAL FORM

Pour-On solution.

4. PACKAGE SIZE

1L, 2.5L, 5L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {dd/mm/yyyy}
Shelf life after first opening the immediate packaging: 6 months.
Once opened use within 6 months, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store upright in original container in order to protect from light.
See package leaflet for full storage conditions.

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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4442

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Solantel 200mg/ml Pour-On Solution 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:

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

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
Statin Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solantel 200mg/ml Pour-On Solution for Cattle
Closantel (as Closantel Sodium Dihydrate)

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

1 ml of solution contains:

Closantel	200 mg
(as Closantel Sodium Dihydrate	217.5 mg)
Brilliant Blue FCF (E133)	0.1 mg

A clear blue/green solution.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

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

Do not use in cattle producing milk for human consumption.

Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

6. ADVERSE REACTIONS

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 animal.

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).

Even though the overall incidence of adverse events is very rare, it has been noted that, when there is an adverse event n 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.

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

7. TARGET SPECIES

Cattle

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

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.

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**
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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 1ml per 10kg bodyweight

9. ADVICE ON CORRECT ADMINISTRATION

Assess bodyweight carefully prior to administration.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.
Shelf life after first opening the container: 6 months
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP'.
The discard date after opening should not exceed the expiry date of the product.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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.

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 absorption of 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.

At doses of three times the recommended dose, no significant clinical signs were recorded. No antidote has been identified for closantel overdose. Symptomatic treatment may be beneficial.

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.

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.

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.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package Quantities:
1L, 2.5L and 5L HDPE backpacks.
Not all pack sizes may be marketed

FOR ANIMAL TREATMENT ONLY

Approved: 16/06/21