DRAFT CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closone 50mg/ml Oral Suspension for Sheep (UK)
Solantel 50mg/ml Oral Suspension for Sheep (BE, ES, FR, IT, PT)
Closantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of product contains:

Closantel:	50 mg
(as Closantel Sodium Dihydrate	54.375mg)

3. PHARMACEUTICAL FORM

Oral suspension
Off-white to yellow suspension.

4. PACKAGE SIZE

1L [2.5L, 5L]

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of chronic and subacute fasciolosis (due to *Fasciola hepatica*).
The product is effective against mature and late immature flukes (from 5 weeks immature).
For the treatment of *Oestrus ovis* (Sheep Nasal Bot Fly).
For the treatment of inhibited, L4 and adult stages of *Haemonchus contortus* .

For further details please refer to the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

10 mg of closantel per kg bodyweight (i.e. 1 ml of product per 5 kg bodyweight).

Read the package leaflet before use.

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
Up to 5kg	1ml	1000	2500	5000
10kg	2ml	500	1250	2500
20kg	4ml	250	625	1250
30kg	6ml	166	416	833
40kg	8ml	125	312	625
50kg	10ml	100	250	500
60kg	12ml	83	208	416
70kg	14ml	71	178	357
80kg	16ml	62	156	312

8. WITHDRAWAL PERIOD

Meat and offal: 42 days
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

User warnings
This product may be irritating to skin and eyes. Wear nitrile rubber gloves when applying the product. Wash hands after use. Read package leaflet before use for full user warnings.

10. EXPIRY DATE

EXP: XX-XX-XXXX
Shelf life after first opening the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Keep the container in the outer carton in order to protect from light.
Store upright in the original container.

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

POM-VPS Prescription Only Medicine – Veterinarian, Pharmacist, SQP

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

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

Distributed by:
Norbrook Laboratories Limited
Unit 1, Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4403

17. MANUFACTURER'S BATCH NUMBER

DRAFT LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closone 50mg/ml Oral Suspension for Sheep (UK)
Solantel 50mg/ml Oral Suspension for Sheep (BE, ES, FR, IT, PT)
Closantel

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1 ml of product contains:

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(as Closantel Sodium Dihydrate	54.375mg)

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1L [2.5L, 5L]

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of chronic and subacute fasciolosis (due to *Fasciola hepatica*).
The product is effective against mature and late immature flukes (from 5 weeks immature).
For the treatment of *Oestrus ovis* (Sheep Nasal Bot Fly).
For the treatment of inhibited, L4 and adult stages of *Haemonchus contortus*.

For further details please refer to the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 42 days
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: XX-XX-XXXX
Shelf life after first opening the container: 28 days.
Once opened, use by: __/__/__

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Keep the container in the outer carton in order to protect from light.
Store upright in the original container.

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

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4403

17. MANUFACTURER'S BATCH NUMBER

DRAFT INSERT TEXT

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closone 50mg/ml Oral Suspension for Sheep (UK)
Solantel 50mg/ml Oral Suspension for Sheep (BE, ES, FR, IT, PT)
Closantel

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

Off-white to yellow suspension.

1 ml of product contains:

Closantel:	50 mg
(as Closantel Sodium Dihydrate	54.375mg)

Excipient(s):

Propylene glycol (E1520)	217.6 mg

4. INDICATION(S)

For the treatment of chronic and subacute fasciolosis (due to *Fasciola hepatica*). The product is effective against mature and late immature flukes (from 5 weeks immature).
For the treatment of *Oestrus ovis* (Sheep Nasal Bot Fly).
For the treatment of inhibited, L4 and adult stages of *Haemonchus contortus*

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

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

7. TARGET SPECIES

Sheep

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

Give orally as a drench.

10 mg of closantel per kg bodyweight (i.e. 1 ml of product per 5 kg bodyweight).
For example:

Bodyweight	*Dose*
Up to 5 kg	1 ml
10 kg	2 ml
20 kg	4 ml
30 kg	6 ml
40 kg	8 ml
50 kg	10 ml
60 kg	12 ml
70 kg	14 ml
80 kg	16 ml

Suitable for use with most types of standard drenching equipment.
Shake well before use.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, bodyweight 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 body weight and dosed accordingly in order to avoid under- or over-dosing.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

10. WITHDRAWAL PERIOD

Meat and offal: 42 days
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.
Do not store above 30°C.
Keep the container in the outer carton in order to protect from light.
Store upright in the original container.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP"
Shelf life after first opening the container: 28 days.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

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.

Resistance to closantel has been reported in *Haemonchus* species outside the EU. 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.

Special precautions for use in animals:

When using a drenching gun, take care not to injure the mouth or pharynx. Do not exceed the stated dose.

The product can be used in all age groups of sheep and lambs.

User Warnings:

This product may be irritating to skin and eyes and users should be careful not to accidentally splash it on themselves or others.

Wear nitrile rubber gloves when applying the product.

In case of accidental spillage onto skin or into eyes, rinse the affected area with large amounts of clean water. If irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

Do not eat, drink or smoke while handling the product.

Other Precautions:

Closantel is very toxic to dung organisms.

Closantel has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of closantel may take place over a period of several weeks. Faeces containing closantel excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

The risk to dung fauna can be reduced by avoiding too frequent and repeated use of closantel (and products of the same anthelmintic class) in sheep and lambs. Animals should not normally be treated in excess of three times a year with closantel.

Use during Pregnancy and Lactation:

The product can be used at any time during pregnancy. It can also be used in rams at any time including during the breeding season. The safety of the product for use during lactation has not been established.

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

Closantel may affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2016

15. OTHER INFORMATION

Closantel is active against benzimidazole resistant strains of *Haemonchus contortus*.

Package Quantities:
White high density polyethylene multidose container backpacks with high density polyethylene screw cap with induction-seal liners.

Pack sizes:
Box with 1 multidose container of 1 litre
Box with 1 multidose container of 2.5 litres
Box with 1 multidose container of 5 litres

Not all pack sizes may be marketed.

ManA 2000

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Norbrook Laboratories Limited
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Approved: 04/08/2016