PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - BASE VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin Solution for Injection for Cattle.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Ivermectin	5 mg
Closantel (as closantel sodium dihydrate)	125 mg
Sodium formaldehyde sulphoxylate	5 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIODS

Meat and offal: 49 days.
Milk: 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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

BN:

Patent No. EP1478372B

10. PACKAGE SIZE

100 ml, 250 ml and 500 ml multidose vials and aluminium caps complete with bromobutyl bungs and aluminium seals. Not all pack sizes may be marketed.

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

User Warnings:

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

Avoid direct contact of the product with the skin. In case of spillage onto the skin rinse immediately with fresh water.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment.

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For Animal Treatment Only.

POM-VPS (‘To be supplied only on veterinary prescription’)

15. MARKETING AUTHORISATION NUMBER

Vm 02000/5008

EXPANDING VIAL LABEL TEXT – PAGE 1

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin Solution for Injection for Cattle.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Ivermectin	5 mg
Closantel (as closantel sodium dihydrate)	125 mg
Sodium formaldehyde sulphoxylate	5 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Read the expanding label before use

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 49 days.
Milk: 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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

BN:

Patent No. EP1478372B

10. PACKAGE SIZE

100 ml, 250 ml and 500 ml multidose vials and aluminium caps complete with bromobutyl bungs and aluminium seals. Not all pack sizes may be marketed.

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

User Warnings:

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

Avoid direct contact of the product with the skin. In case of spillage onto the skin rinse immediately with fresh water.
Wash hands after use.
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In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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Medicines should not be disposed of via wastewater.
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14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For Animal Treatment Only.

POM-VPS (‘To be supplied only on veterinary prescription’)

15. MARKETING AUTHORISATION NUMBER

Vm 02000/5008

VIAL LABEL TEXT – PAGES 2 - 5

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin Solution for Injection for Cattle.

2. COMPOSITION

Each ml contains:

Ivermectin	5 mg
Closantel (as closantel sodium dihydrate)	125 mg
Sodium formaldehyde sulphoxylate	5 mg

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of cattle.

Gastrointestinal roundworms

Ostertagia ostertagi (including inhibited larval stages), *Ostertagia lyrata* (adult), *Haemonchus placei* (adult and immature), *Trichostrongylus axei* (adult and immature), *Trichostrongylus colubriformis* (adult and immature), *Cooperia oncophora* (adult and immature), *Cooperia punctata* (adult and immature), *Cooperia pectinata* (adult and immature), *Oesophagostomum radiatum* (adult and immature), *Nematodirus helvetianus* (adult), *Nematodirus spathiger* (adult), *Strongyloides papillosus* (adult), *Bunostomum phlebotomum* (adult and immature), *Toxocara vitulorum* (adult), *Trichuris* spp.

Lungworms

Dictyocaulus viviparus (adult and 4th stage larvae)

Liver Fluke (trematodes)

Fasciola gigantica, Fasciola hepatica

Treatment of fluke at 12 weeks (mature) >99% efficacy

Treatment of fluke from 7 weeks (late immature) >90% efficacy

Eyeworms (adult)

Thelazia spp.

Cattle grubs (parasitic stages)

Hypoderma bovis, Hypoderma lineatum

Lice

Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

Mange Mites

*Psoroptes ovis (*syn *P communis* var *bovis), Sarcoptes scabiei* var *bovis*

The veterinary medicinal product may also be used as an aid in the control of the biting louse *Damalinia bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity:

The veterinary medicinal product, at the recommended dose, controls re-infection with:

	Prolonged activity
Dictyocaulus viviparus	Up to 21 days
Ostertagia ostertagi	Up to 21 days
Oesophagostomum radiatum	Up to 21 days
Cooperia spp	Up to 14 days
Trichostrongylus axei	Up to 14 days
Haemonchus placei	Up to 14 days

5. CONTRAINDICATIONS

This product is not for intravenous or intramuscular use.
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.
Avermectins may not be well tolerated in all non target species (cases of intolerance with fatal outcome are reported in dogs – especially Collies, Bobtails, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

6. SPECIAL WARNING(S)

Special warnings:
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.
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.

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.
Resistance to ivermectin has been reported in *Cooperia* spp in cattle. Therefore the use of this product should be based on local epidemiological information about the susceptibility of the *Cooperia* spp and recommendations on how to limit further selection for resistance to anthelmintics.
Overdose:
Symptoms of serious closantel overdose are decreased vision or blindness, anorexia, incoordination and general weakness, convulsions, tachycardia and in extreme cases death.

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. However where used as directed there are unlikely to be any untoward effects. Signs of overdosage can include loss of appetite, decreased vision, loose faeces and increased frequency of defaecation. High doses may cause blindness, hyperventilation, hyperthermia, general weakness, inco-ordination, convulsions, tachycardia and in extreme cases death. Treatment of overdosage is symptomatic as no antidote has been identified.Interactions with other medicinal products and other forms of interaction:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. Do not administer concomitantly with chlorinated compounds. The effect of GABA agonists are increased by ivermectin. Please refer to contraindication section.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink while handling the product.
Avoid direct contact of the product with the skin. In case of spillage onto the skin rinse immediately with fresh water.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Ivermectin is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/herd health, as advised by a veterinarian.
For Animal Treatment Only.
Keep out of the sight and reach of children.

Pregnancy and lactation:
The veterinary medicinal product can be administered to cattle at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

7. ADVERSE EVENTS

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Common (1 to 10 animals / 100 animals treated):	Injection site pain[2]

[1]Tissue swellings at the injection site are common up to 48 hours after injection.
[2]Injection site pain is common and will resolve thereafter without treatment. Hardness on palpation may be observed up to 7 days following administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system. See 'Contact details' section of the package leaflet.

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

Bodyweight and dosage should be accurately determined prior to treatment to avoid underdosing.
The veterinary medicinal product should be administered at a dosage rate of 200 mcg ivermectin per kg and 5 mg closantel per kg bodyweight. A sterile 16-gauge, one-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

It should be injected subcutaneously in the middle portion of the neck using the aseptic technique. A maximum dose of 10ml should be administered at any one site with any residual volume administered at another site in the neck. The first dose should be injected into the right neck with any residual volumes injected into separate sites on the left and right neck

Bodyweight (kg)	**Dose Volume (ml)**
Up to 25	1
26 - 50	2
51 - 75	3
76 - 100	4
101 - 125	5
126 - 150	6
151 - 175	7
176 - 200	8
201 - 225	9
226 - 250	10
251 - 275	11
276 - 300	12

Over 300 kg bodyweight give 1 ml per 25 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

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.
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 bodyweight and dosed accordingly, in order to avoid under- or overdosing.
Do not exceed 40 broachings per vial. If more than 40 broachings are required, use of a draw off needle is recommended.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 49 days.
Milk: 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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Protect from light.
This product does not contain a preservative.
Use of a draw-off needle is recommended to avoid excess broaching of the stopper.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the container: When the container is broached (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.
Discard unused material.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
This veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/5008

Pack sizes
100ml, 250ml and 500ml

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

March 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

16. CONTACT DETAILS

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
105 Armagh Road,
Newry, Co. Down, BT35 6PU
Northern Ireland

Contact details to report suspected adverse reactions:
Email address: phvdept@norbrook.co.uk
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION MODE OF ACTION

Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids and insects by its effect on the nervous system of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.

Closantel is a member of the salicylanilide class of anthelmintics. Salicylanilides are hydrogen ionophores which act as potent uncouplers of oxidative phosphorylation. The site of action of these proton ionophores is known to be selective uncoupling of oxidative phosphorylation in parasite mitochondria.

Treatment with the veterinary medicinal product when flukes are five weeks and greater has been shown to reduce subsequent reproductive capacity and egg shedding.

The veterinary medicinal product is packed in 100 ml, 250 ml and 500 ml multidose vials and aluminium caps complete with bromobutyl bungs and aluminium seals. Not all pack sizes may be marketed.

Distributed in the UK by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down, BT35 6QQ
Northern Ireland

Vm 02000/5008

POM-VPS

To be supplied only on veterinary prescription.

Approved: 18 August 2023