PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Solution For Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A solution for injection containing 0.5% w/v ivermectin, 12.5% w/v closantel and 0.5% w/v Sodium Formaldehyde Sulphoxylate.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml / 250 ml / 500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Inject subcutaneously at a dosage rate of 0.2 mg ivermectin/kg bodyweight and 5 mg closantel/kg bodyweight (1 ml per 25 kg), into the neck. A maximum dose of 10 ml 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.

8. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. 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. Do not use any closantel-containing products during the 49 day withdrawal period. If an ivermectin-only product is used during this period, the withdrawal periods for all products must be observed.

9. SPECIAL WARNING(S), IF NECESSARY

The product should not be used in cattle producing milk for human consumption.
This product is not for intravenous or intramuscular use. Should any apparent growth or discoloration occur the product should be discarded. Do not smoke, eat or drink while handling the product. Direct contact of the product with the skin should be kept to a minimum. 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. This product does not contain a preservative. Avoid introduction of contamination during use and should any growth or discoloration occur the product should be discarded.

10. EXPIRY DATE

EXP: dd/mm/yy

Discard 28 days after first removing a dose

Discard by: _____ / _____ / _____

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 products should be disposed of in accordance with local requirements.

13. 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Newry
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4273
ManA 2000

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

Patent No. EP1478372B

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Chemical Group of Anthelmintic Endectocides [3-AV]

***IMPORTANT: READ EXPANDING LABEL BEFORE USE.**

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

BASE PAGE

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

Norbrook Laboratories Limited
Newry
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Solution for Injection

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

A solution for injection containing 0.5% w/v ivermectin, 12.5% w/v closantel and 0.5% w/v Sodium Formaldehyde Sulphoxylate.

4. PHARMACEUTICAL FORM

Solution for Injection

5. PACKAGE SIZE

100 ml / 250 ml / 500 ml

6. INDICATION(S)

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

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle

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

Inject subcutaneously at a dosage rate of 0.2 mg ivermectin/kg bodyweight and 5 mg closantel/kg bodyweight (1 ml per 25 kg), into the neck. A maximum dose of 10 ml 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.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. 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. Do not use any closantel-containing products during the 49 day withdrawal period. If an ivermectin-only product is used during this period, the withdrawal periods for all products must be observed.

13. SPECIAL STORAGE PRECAUTIONS

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

14. SPECIAL WARNING(S)

The product should not be used in cattle producing milk for human consumption.
This product is not for intravenous or intramuscular use. Should any apparent growth or discoloration occur the product should be discarded. Do not smoke, eat or drink while handling the product. Direct contact of the product with the skin should be kept to a minimum. 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. This product does not contain a preservative. Avoid introduction of contamination during use and should any growth or discoloration occur the product should be discarded.

15. EXPIRY DATE

EXP: dd/mm/yy

Discard 28 days after first removing a dose

Discard by: _____ / _____ / _____

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-VPS

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19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4273
ManA 2000

21. MANUFACTURER'S BATCH NUMBER

B.N:
DOM:

22. OTHER INFORMATION

Patent No. EP1478372B

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Chemical Group of Anthelmintic Endectocides [3-AV]

***IMPORTANT: READ EXPANDING LABEL BEFORE USE.**

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

EXPANDING LABEL (PAGE 1)

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

Norbrook Laboratories Limited
Newry
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Solution for Injection

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

A solution for injection containing 0.5% w/v ivermectin, 12.5% w/v closantel and 0.5% w/v Sodium Formaldehyde Sulphoxylate.

4. PHARMACEUTICAL FORM

Solution for Injection

5. PACKAGE SIZE

100 ml / 250 ml / 500 ml

6. INDICATION(S)

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

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle

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

Inject subcutaneously at a dosage rate of 0.2 mg ivermectin/kg bodyweight and 5 mg closantel/kg bodyweight (1 ml per 25 kg), into the neck. A maximum dose of 10 ml 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.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. 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. Do not use any closantel-containing products during the 49 day withdrawal period. If an ivermectin-only product is used during this period, the withdrawal periods for all products must be observed.

13. SPECIAL STORAGE PRECAUTIONS

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

14. SPECIAL WARNING(S)

The product should not be used in cattle producing milk for human consumption.
This product is not for intravenous or intramuscular use. Should any apparent growth or discoloration occur the product should be discarded. Do not smoke, eat or drink while handling the product. Direct contact of the product with the skin should be kept to a minimum. 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. This product does not contain a preservative. Avoid introduction of contamination during use and should any growth or discoloration occur the product should be discarded.

15. EXPIRY DATE

EXP: dd/mm/yy

Discard 28 days after first removing a dose

Discard by: _____ / _____ / _____

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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20. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4273
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21. MANUFACTURER'S BATCH NUMBER

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22. OTHER INFORMATION

Patent No. EP1478372B

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Chemical Group of Anthelmintic Endectocides [3-AV]

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EXPANDING LABEL (PAGE 2-5)

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

Norbrook Laboratories Limited
Newry
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Solution for Injection

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

A solution for injection containing 0.5% w/v ivermectin, 12.5% w/v closantel and 0.5% w/v Sodium Formaldehyde Sulphoxylate.

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

Norofas Solution for Injection is available in three ready-to-use sizes – 100 ml, 250 ml and 500 ml volumes. Not all pack sizes may be marketed.

6. INDICATION(S)

For the treatment of mixed trematode (liver fluke) and nematode or arthropod infestations due to gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice of cattle. One dose of Norofas Solution for Injection effectively controls internal and external parasites that impair the health and productivity 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 at 9 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*

Norofas Solution for Injection 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.

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 Norofas Solution for Injection when flukes are five weeks and greater has been shown to reduce subsequent reproductive capacity and egg shedding.

PRODUCT ADVANTAGES

Low-Volume Injection
Norofas Solution for Injection is highly effective against internal and external parasites at a dose volume of 1 ml per 25 kg bodyweight in cattle. It can be administered quickly and easily.

Broad Spectrum

Norofas Solution for Injection provides broad-spectrum efficacy against internal and external parasites of cattle.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle

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

To ensure administration of a correct dose, body weight 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 overdosing.

Norofas Solution for Injection should be administered at a dosage rate of 200 mcg ivermectin per kg and 5 mg closantel per kg bodyweight. It should be injected subcutaneously in the middle portion of the neck using the aseptic technique. A maximum dose of 10 ml 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. A sterile 16-gauge, one-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

Bodyweight (kg)	**Dose Volume (ml)**
Up to 50	2
51 - 100	4
101 - 150	6
151 - 200	8
201 - 250	10
251 - 300	12

Over 300 kg bodyweight give 1 ml per 25 kg bodyweight

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a Suitably Qualified Person.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. 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. Do not use any closantel-containing products during the 49 day withdrawal period. If an ivermectin-only product is used during this period, the withdrawal periods for all products must be observed.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from light.

14. SPECIAL WARNING(S)

Animals must not be slaughtered for human consumption during treatment. Do not use in cattle producing milk for human consumption.

This product is not for intravenous or intramuscular use.
Do not smoke, eat or drink while handling the product. Direct contact of the product with the skin should be kept to a minimum. 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.

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs – especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

Transitory discomfort has been observed in some cattle following subcutaneous administration. Tissue swellings at the injection site have been observed. These reactions resolve without treatment.

Do not use in cases of known hypersensitivity to the active ingredient.

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.

This product does not contain a preservative.
Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur, the product should be discarded.

Use of a draw-off needle is recommended to avoid excess broaching of the stopper.
After first use, discard the vial within 28 days. This date should be recorded on the label. Discard unused material.

Overdose: Symptoms of serious closantel overdose are decreased vision or blindness, anorexia, incoordination and general weakness.

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 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.

15. EXPIRY DATE

EXP: dd/mm/yy

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

LEGAL CATEGORY:

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription**.**

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4273

21. MANUFACTURER'S BATCH NUMBER

B.N:
DOM:

22. OTHER INFORMATION

Further information for the treatment programmes for mixed infestations consisting of nematodes and/or ectoparasite concurrent with fluke.
The treatment schedule should be based on the local epidemiological situation. The dosing programme should be established by a suitably qualified person. Observe minimum interdosing periods due to possible closantel accumulation.

NOTE TO USER
Ivermectin belongs to the avermectin [3-AV] class of anthelmintics in the endectocides. Chemical group of anthelmintic endectocides [3-AV]. Closantel is a member of the salicylanilide class of anthelmintics.

DISTRIBUTED BY:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Patent No.: EP1478372B

Approved: 10/10/2017