DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin	5 mg/mL
Closantel	200 mg/mL
Brilliant Blue FCF (E133)	0.1 mg/mL

3. PHARMACEUTICAL FORM

Pour-On solution.

4. PACKAGE SIZE

250mL [500mL, 1L, 2.5L, 5L]

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The product should be administered topically at a dosage rate of 500 μg ivermectin per kg bodyweight and 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.

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				
		250ml	500ml	1 litre	2.5 litre	5 litre
100kg*	10ml	25	50	100	250	500
150kg	15ml	16	33	66	166	333
200kg	20ml	12	25	50	125	250
250kg	25ml	10	20	40	100	200
300kg	30ml	8	16	33	83	166
350kg	35ml	7	14	28	71	142
400kg	40ml	6	12	25	62	125
450kg	45ml	5	11	22	55	111
500kg	50ml	5	10	20	50	100
550kg	55ml	4	9	18	45	90
600kg	60ml	4	8	16	41	83

* Dose rate 1ml per 10kg bodyweight

8. WITHDRAWAL PERIOD

Meat and offal: 58 days.

Milk: 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.

Due to the significant likelihood of 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 residues violations in non-treated animals.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Special precautions for use in animals:

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.

Care should be taken when treating animals which may be of low nutritional status as this may increase susceptibility of adverse events occurring.

In very rare cases (less than 1 animal in 10,000 animals, 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product may be irritating to human skin and eyes or cause hypersensitivity. Avoid skin and/or eye contact with the product during treatment, when handling recently treated animals or when cleaning the used equipment. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. 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 get medical attention.

This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. Do not eat, drink or smoke whilst handling the product. If accidental ingestion occurs, get medical attention and show the package leaflet to the physician. Wash hands after use. This product is flammable. Keep away from sources of ignition. Use only in well ventilated areas or outdoors.

Other precautions:

The product 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 repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

10. EXPIRY DATE

XX-XX-XXXX

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store upright in original container.
Protect from light.
Discard unused material. Avoid introduction of contamination.
Replace the cap securely after use.
If stored at temperatures below 0°C, Norofas Pour-On Solution for Cattle 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.

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 REACH AND SIGHT 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

Vm: 02000/4312

17. MANUFACTURER'S BATCH NUMBER

BN:

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

To be supplied only on veterinary prescription

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

On Behalf of:
Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

UK Patent: GB 2,403,905B
WO 2005/007241 "patent pending"

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin	5 mg/mL
Closantel	200 mg/mL
Brilliant Blue FCF (E133)	0.1 mg/mL

3. PHARMACEUTICAL FORM

Pour-On Solution

4. PACKAGE SIZE

250mL [500mL, 1L, 2.5L, 5L]

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 58 days.
Milk: 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.
Due to the significant likelihood of 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 residues violations in non-treated animals.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

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Protect from light.
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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

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

To be supplied only on veterinary prescription.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Station Works
Camlough Road
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BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

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17. MANUFACTURER'S BATCH NUMBER

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Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

UK Patent: GB 2,403,905B
WO 2005/007241 "patent pending"

DRAFT INSERT TEXT

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

Marketing Authorisation Holder and manufacturer responsible for Batch Release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofas Pour-On Solution for Cattle.

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

Ivermectin	5 mg/mL
Closantel	200 mg/mL
Brilliant Blue FCF (E133)	0.1 mg/mL

4. INDICATION(S)

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

Gastrointestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp*, Oesophagostomum radiatum, Nematodirus helvetianus* (adult), *Strongyloides papillosus* (adult).

Lungworms (adult and fourth stage larvae)
Dictyocaulus viviparus

Trematodes (adult and late immatures)
Fasciola gigantica
Fasciola hepatica
Treatment of fluke at 12 weeks (mature)
Treatment of fluke at 7 weeks (late immature)

Eyeworms (adult)
Thelazia spp

Cattle grubs (parasitic stages)
Hypoderma bovis, Hypoderma lineatum

Lice
Linognathus vituli, Haematopinus eurysternus, Damalinia bovis

Mange Mites
Chorioptes bovis, Sarcoptes scabiei var *bovis*

5. CONTRAINDICATIONS

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

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals, 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.

If you notice any side effects even those not already listed in this leaflet, or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

The product should be administered topically at a dosage rate of 500 μg ivermectin per kg bodyweight and 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. A dosing programme should be established by a veterinary professional.

9. ADVICE ON CORRECT ADMINISTRATION

Assess bodyweight carefully prior to administration.

10. WITHDRAWAL PERIOD

Meat and offal: 58 days.
Milk: 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.
Due to the significant likelihood of 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 residues violations in non-treated animals.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Discard unused material. Avoid introduction of contamination.
Replace the cap securely after use.
Keep out of the sight and reach of children.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.
Store upright in original container.
Do not use after expiry date stated on label and carton after 'EXP'.

If stored at temperatures below 0°C, Norofas Pour-On Solution for Cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

12. SPECIAL WARNINGS

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.

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.

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

Due to the significant likelihood of 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 residues violations (see section 10) or in very rare cases, it can lead to adverse events (see section 6) in non-treated animals.

It is not advisable to administer the product when *Hypoderma lineatum* larvae are localised in the periaesophagic region, or when *Hypoderma bovis* larvae are situated in the spinal canal. Seek professional veterinary advice to determine the best period of use.

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.

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This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. Do not eat, drink or smoke whilst handling the product. If accidental ingestion occurs, get medical attention and show the package leaflet to the physician. Wash hands after use. This product is flammable. Keep away from sources of ignition. Use only in well ventilated areas or outdoors.

Other precautions:

The product 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 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. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2022

15. OTHER INFORMATION

Package Quantities:
250mL, 500mL and 1L containers and 1L, 2.5L and 5L backpacks.
Not all package sizes may be marketed

ManA 2000
Vm: 02000/4312

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

To be supplied only on veterinary prescription.

Distributed by:
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Newry
BT35 6QQ, Co Down
Northern Ireland

On Behalf of:
Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

UK Patent: GB 2,403,905B
WO 2005/007241 “patent pending”

Approved: 03 January 2023