<PARTICULARS TO APPEAR ON THE OUTER PACKAGE
250ml, 1L, 2.5L, 5L>

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norador 5mg/ml Pour-on Solution for Cattle
Doramectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Doramectin: 5 mg
Brilliant blue FCF (E133): 0.007 mg

3. PHARMACEUTICAL FORM

Pour-on Solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.
READ PACKAGE LEAFLET BEFORE USE.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

A single treatment of 500 µg of doramectin/kg bodyweight equivalent to 1 ml of product per 10 kg bodyweight, applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.
FOR EXTERNAL USE ONLY

READ PACKAGE LEAFLET BEFORE USE.

DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*					
BODYWEIGHT	DOSE PER ANIMAL	NUMBER OF FULL DOSES PER PACK					
		250ml	1 litre	2.5 litre	5 litre	10 litre	20 litre
100kg	10ml	25	100	250	500	1000	2000
150kg	15ml	16	66	166	333	666	1333
200kg	20ml	12	50	125	250	500	1000
250kg	25ml	10	40	100	200	400	800
300kg	30ml	8	33	83	166	333	666
350kg	35ml	7	28	71	142	285	571
400kg	40ml	6	25	62	125	250	500
450kg	45ml	5	22	55	111	222	444
500kg	50ml	5	20	50	100	200	400
550kg	55ml	4	18	45	90	181	363
600kg	60ml	4	16	41	83	166	333

* Dose rate 1ml per 10kg bodyweight

8. WITHDRAWAL PERIOD

Withdrawal Period
Meat and offal: 35 days.

Not permitted for use in lactating animals producing milk for human consumption. Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months (60 days) of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

PRECAUTIONS: HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

User Warnings: Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Use only in well ventilated areas or outdoors. Read package leaflet before use for full user warnings.

10. EXPIRY DATE

EXP: XX-XX-XXXX
Once opened, use by……...
Shelf-life after first broaching the container: 3 months.

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Do not refrigerate.
Store in tightly closed original container.
Avoid introduction of contamination.
Do not use after the expiry date which is stated on the carton or label after “EXP”.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material 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

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 Ltd
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4359

17. MANUFACTURER’S BATCH NUMBER

<PACKAGE LEAFLET 250ml, 1L, 2.5L, 5L>
<PARTICULARS TO APPEAR ON THE EXPANDING LABEL 10L, 20L>

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
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norador 5mg/ml Pour-on Solution for Cattle
Doramectin

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

Each ml contains:
Doramectin: 5 mg
Brilliant blue FCF (E133): 0.007 mg
A pale blue, clear pour-on solution.

4. INDICATION(S)

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornflies in cattle.

Gastrointestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (inc. inhibited larvae)
O. lyrata[1]
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata[1]
C. surnabada[1] *(syn. mcmasteri)*
Bunostomum phlebotomum[1]
Oesophagostomum radiatum
Trichuris spp[1]
[1] adults

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus
Eyeworms (adults)
Thelazia spp
Warbles (parasitic stages)
Hypoderma bovis, H. lineatum
Biting lice
Damalinia (Bovicola) bovis
Sucking lice
Haematopinus eurystemus,
Linognathus vituli,
Solenopotes capillatus
Mange mites
Psoroptes bovis,
Sarcoptes scabiei,
Chorioptes bovis
Horn fly
Haematobia irritans

Duration of activity

The veterinary product protects cattle against infection or re-infection with the following parasites for the periods indicated.

Species	Days
Ostertagia ostertagi	35
oncophora Cooperia	28
Dictyocaulus viviparus	42
Linognathis vituli	49
Oesophagostomum radiatum	21
Damalinia (Bovicola) bovis	42
Trichostrongylus axei	28
Solenopotes capillatus	35

The veterinary product also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

5. CONTRAINDICATIONS

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 , may occur. Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving.

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

6. ADVERSE REACTIONS

In rare cases, (more than 1 but less than 10 animals in 10,000 animals treated) small skin lesions may occur at the administration site.

7. TARGET SPECIES

Cattle

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

Dosage: A single treatment of 1 ml (5mg of doramectin) per 10 kg bodyweight (based on a recommended dosage level of 500 µg doramectin per kg bodyweight).

Administration:
For topical use: pour-on application
The formulation should be applied along the mid line of the back in a narrow strip between the withers and tailhead.

The veterinary product will be supplied in:

- 250mL and 1L standard high density polyethylene bottles with 28mm polypropylene/high density polyethylene caps for use with dosing cups.

- 1L, 2.5L and 5L white flat bottomed heavy duty high density polyethylene back-packs with 38mm white polypropylene easy peel caps for use with a dosing gun delivery system.

- 10L and 20L white high density polyethylene Jerry cans with high density polyethylene caps for use with a dosing gun delivery system.

9. ADVICE ON CORRECT ADMINISTRATION

DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING* NUMBER OF FULL DOSES PER PACK					
BODYWEIGHT	**DOSE PER ANIMAL**	**250ml**	**1 litre**	**2.5 litre**	**5 litre**	**10 litre**	**20 litre**
100kg	10ml	25	100	250	500	1000	2000
150kg	15ml	16	66	166	333	666	1333
200kg	20ml	12	50	125	250	500	1000
250kg	25ml	10	40	100	200	400	800
300kg	30ml	8	33	83	166	333	666
350kg	35ml	7	28	71	142	285	571
400kg	40ml	6	25	62	125	250	500
450kg	45ml	5	22	55	111	222	444
500kg	50ml	5	20	50	100	200	400
550kg	55ml	4	18	45	90	181	363
600kg	60ml	4	16	41	83	166	333

* Dose rate 1ml per 10kg bodyweight

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- and over- dosing.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

10. WITHDRAWAL PERIOD

Meat and offal: 35 days.
Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months (60 days) of expected parturition..

11. SPECIAL STORAGE PRECAUTIONS

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

Protect from light.
Do not refrigerate.
Store in tightly closed original container.
Avoid introduction of contamination.

Do not use after the expiry date which is stated on the carton or label after "EXP".
Shelf life after first broaching the container: 3 months.
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

For external use only.

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.
- under dosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of a dosing device (if any).

Resistance to doramectin and other avermectins has been reported in gastro-intestinal nematodes, especially *Cooperia oncophera* and *Ostertagia ostertagi*, in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of the target nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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 a different pharmacological class and having a different mode of action should be used.

Do not apply to areas of skin that are contaminated with mud or manure.

Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.

Special precautions for use

i. Special precautions for use in animals.

Avermectins may not be well tolerated in non-target species. Cases of intolerance with fatal outcome have been reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in chelonia(turtles and tortoise). Care should be taken to avoid ingestion of spilled product or access to containers by these other species.

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

ii. User warnings.

Persons with known hypersensitivity to the active substance should avoid contact with the product. Do not smoke or eat while handling the product. Wash hands after use. The product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons. Operators should wear 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. Use only in well ventilated areas or outdoors.

Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

iii. Other precautions

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments. Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. The risk to aquatic systems and dung fauna can be reduced by avoiding too frequent and repeated use of doramectin (and products of the same anthelmintic class in cattle). The risk to aquatic ecosystems will be reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

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

Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.
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

15. OTHER INFORMATION

The veterinary product is available in 250 ml and 1L, containers, 1L, 2.5L and 5L back-packs, 10L and 20L Jerry cans. Not all package sizes may be marketed.

When the container is opened for the first time, using the in-use shelf-life which is specified on the label, 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

Legal category

Distributed by:

FOR ANIMAL TREATMENT ONLY

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE 250ml, 1L, 2.5L, 10 L, 20L, >

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norador 5mg/ml Pour-on Solution for Cattle
Doramectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Doramectin: 5 mg
Brilliant blue FCF (E133): 0.007 mg

3. PHARMACEUTICAL FORM

Pour-on Solution

4. PACKAGE SIZE

250 mL [1L, 2.5L, 5L, 10L, 20L]

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

READ PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIOD

Withdrawal Period
Meat and offal: 35 days.
Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months (60 days) of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

READ PACKAGE LEAFLET BEFORE USE.

10. EXPIRY DATE

EXP: XX-XX-XXXX
Once opened, use by……...
Shelf life after first broaching the container: 3 months.

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Do not refrigerate.
READ PACKAGE LEAFLET BEFORE USE.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

READ 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

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 Ltd
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4359

17. MANUFACTURER'S BATCH NUMBER

Approved: 18 January 2019