ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

250 Ml (SND), 1L (SND), 1L (Backpack), 2.5L (Backpack), 5L (Backpack), 10L (Jerry can) - Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tauramox 5 mg/ml Pour-On Solution for Cattle
Moxidectin

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 5 mg

3. PHARMACEUTICAL FORM

Pour-On Solution

4. PACKAGE SIZE

250mL(Single Neck Dispenser)
1L (Single Neck Dispenser)
1L (Backpack)
2.5L (Backpack)
5L (Backpack)
10L (Jerry can)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

READ PACKAGE LEAFLET BEFORE USE

For the treatment of mixed nematodes or arthropod infestations due to roundworms, lungworms, warbles, mites, lice and horn flies of cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

READ PACKAGE LEAFLET BEFORE USE

FOR CUTANEOUS APPLICATION ONLY

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

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**
100kg*	10ml	25	100	250	500	1000
150kg	15ml	16	66	166	333	666
200kg	20ml	12	50	125	250	500
250kg	25ml	10	40	100	200	400
300kg	30ml	8	33	83	166	333
350kg	35ml	7	28	71	142	285
400kg	40ml	6	25	62	125	250
450kg	45ml	5	22	55	111	222
500kg	50ml	5	20	50	100	200
550kg	55ml	4	18	45	90	181
600kg	60ml	4	16	41	83	166

* Dose rate 1ml per 10kg bodyweight

8. WITHDRAWAL PERIOD

Cattle: meat and offal -14 days
milk -6 days (144 hours)

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, a waterproof coat and boots when applying the product. Use only in well ventilated areas or outdoors. Read package leaflet before use for full user warnings.

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms:

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period more than 2 weeks and may decrease dung fly abundance during that period. It has been established in laboratory tests that moxidectin may temporarily affect dung beetle reproduction; however, field studies indicate no-long term effects. Nevertheless, in case of repeated treatments with moxidectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

- Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

NB: Or, in case of insufficient space on the label:

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

EXP: XX-XX-XXXX
Once opened, use by:
Shelf-life after first opening the container: 6 months.
Do not use after the expiry date listed on the carton after “EXP”

11. SPECIAL STORAGE CONDITIONS

Store in original container.
Protect from light.

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

Extremely dangerous for fish and aquatic life. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

(IE) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4406

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 mL (SND), 1L (SND), 1L (Backpack), 2.5L (Backpack), 5L (Backpack), 10L (Jerry can) - Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tauramox 5 mg/ml Pour-On Solution for Cattle
Moxidectin

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 5 mg

3. PHARMACEUTICAL FORM

Pour-On Solution.

4. PACKAGE SIZE

250mL (Single Neck Dispenser)
1L (Single Neck Dispenser)
1L (Backpack)
2.5L (Backpack)
5L (Backpack)
10L (Jerry can)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

READ PACKAGE LEAFLET BEFORE USE

For the treatment of mixed nematodes or arthropod infestations due to roundworms, lungworms, warbles, mites, lice and horn flies of cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

READ PACKAGE LEAFLET BEFORE USE

FOR CUTANEOUS APPLICATION ONLY

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

8. WITHDRAWAL PERIOD

Cattle: meat and offal -14 days
milk -6 days (144 hours)

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, a waterproof coat and boots when applying the product. Use only in well ventilated areas or outdoors. Read package leaflet before use for full user warnings.

Environmental Warnings: Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms:

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period more than 2 weeks and may decrease dung fly abundance during that period. It has been established in laboratory tests that moxidectin may temporarily affect dung beetle reproduction; however, field studies indicate no-long term effects. Nevertheless, in case of repeated treatments with moxidectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

- Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

NB: Or, in case of insufficient space on the label:

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

EXP: XX-XX-XXXX
Once opened, use by:
Shelf-life after first opening the container: 6 months.
Do not use after the expiry date listed on the carton after “EXP”

11. SPECIAL STORAGE CONDITIONS

Store in original container.
Protect from light.

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

Extremely dangerous for fish and aquatic life. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

(IE) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4406

17. MANUFACTURER'S BATCH NUMBER

BN:

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

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:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

Manufacturer responsible for batch release:
(EU)
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tauramox 5 mg/ml Pour-On Solution for Cattle
Moxidectin

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

Each ml contains:

Moxidectin	5 mg
Tertiary Butylhydroquinone (E319)	0.03 mg
Butylhydroxyanisole (E320)	0.1 mg

A translucent, colourless to pale yellow slightly viscous solution.

4. INDICATION(S)

For the treatment of infections of cattle with parasites sensitive to moxidectin, caused by:

- Adult and larval gastro-intestinal nematodes:
Haemonchus placei, Ostertagia ostertagi (including inhibited larvae)*, Trichostrongylus axei, Nematodirus helvetianus, Cooperia oncophora, Cooperia punctata* (adults)*, Oesophagostomum radiatum* (adults)*, Bunostomum phlebotomum* (adults)

- Adult respiratory tract nematode
Dictyocaulus viviparus

- Warbles (migrating larvae)
Hypoderma bovis, Hypoderma lineatum

- Lice
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Bovicola bovis (Damalinia bovis)

- Mange Mites
Sarcoptes scabiei, Psoroptes ovis, Chorioptes bovis

- Horn Flies
Haematobia irritans

The product has a persistent effect in preventing against reinfection by:
Ostertagia ostertagi for 5 weeks
Dictyocaulus viviparus for 6 weeks.

5. CONTRAINDICATIONS

Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

Reactions at the site of application may occur after application on extremely rare occasions. Neurological signs (including ataxia, trembling and lethargy) have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cattle

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

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

This product has been formulated only for external application to cattle, do not use in other species.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a veterinary professional.

9. ADVICE ON CORRECT ADMINISTRATION

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**
100kg*	10ml	25	100	250	500	1000
150kg	15ml	16	66	166	333	666
200kg	20ml	12	50	125	250	500
250kg	25ml	10	40	100	200	400
300kg	30ml	8	33	83	166	333
350kg	35ml	7	28	71	142	285
400kg	40ml	6	25	62	125	250
450kg	45ml	5	22	55	111	222
500kg	50ml	5	20	50	100	200
550kg	55ml	4	18	45	90	181
600kg	60ml	4	16	41	83	166

* Dose rate 1ml per 10kg bodyweight

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

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

Cattle: meat and offal -14 days
milk -6 days (144 hours).

11. SPECIAL STORAGE PRECAUTIONS

Store in original container.
Protect from light.
Shelf life after first opening the immediate packaging: 6 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the container and carton after “EXP”
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

Special warnings for each target species
The product can be administered to cattle (including dairy, beef/suckler cattle) at any stage of pregnancy or lactation.

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.

Partial cross-resistance between ivermectin and moxidectin has been reported in nematode parasites. Cases of resistance to moxidectin have been reported in gastrointestinal nematode parasites of cattle, in the EU and elsewhere. Therefore use of this product should be based on local (regional, farm) epidemiological information about susceptibility of parasites, local history of treatments and recommendations on how to limit further selection for resistance to anthelmintics.

Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms of overdose have been observed with the product given at ten times the recommended dose.
They are manifested as transient salivation, depression, drowsiness and ataxia. There is no specific antidote.

Special precautions for use in animals.
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.
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 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.

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

Avoid direct contact with skin and eyes. The product may be irritating to skin and eyes and users should be careful not to apply it to themselves or to other people.
Wear safety glasses, 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 irritation persists, seek medical attention.
If accidental eye exposure occurs, immediately rinse the eyes thoroughly with water and seek medical attention.
Avoid getting the product in your mouth.
Do not smoke or eat whilst handling the product. Wash hands after use.
Avoid accidental inhalation of this product. Use only in well ventilated areas or outdoors.
Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

Other precautions regarding impact on the environment

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance, In particular, in acute and chronic toxicity studies with algae, crustaceans and fish, moxidectin showed toxicity to these organisms, yielding the following endpoints:

Organism		**EC_{50}**	**NOEC**
Algae	*S. capricornutum*	>86.9 µg/l	86.9 µg/l
Crustaceans (Water fleas)	*Daphnia magna* (acute)	0.0302 µg/l	0.011 µg/l
	Daphnia magna (reproduction)	0.0031 µg/l	0.010 µg/l
Fish	*O. mykiss*	0.160 µg/l	Not determined
	L. macrochirus	0.620 µg/l	0.52 µg/l
	P. promelas (early life stages)	Not applicable	0.0032 µg/l
	Cyprinus carpio	0.11 µg/l	Not determined

EC_{50}: the concentration which results in 50% of the test species individuals being adversely affected, i.e. both mortality and sub-lethal effects.
NOEC: the concentration in the study at which no effects are observed.

This implies that when allowing moxidectin to enter water bodies, this may have a severe and lasting impact on aquatic life. To mitigate this risk, all precautions for use and disposal must be adhered to.
Therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms:

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period more than 2 weeks and may decrease dung fly abundance during that period. It has been established in laboratory tests that moxidectin may temporarily affect dung beetle reproduction; however, field studies indicate no-long term effects. Nevertheless, in case of repeated treatments with moxidectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

- Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

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

Extremely dangerous for fish and aquatic life. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

15. OTHER INFORMATION

The product is available in 250ml (single neck dispenser), 1L (Back-pack and single neck dispenser), 2.5L (Back-pack), 5L (Back-pack) and 10L (Jerry can) fluorinated high-density polyethylene containers.

Not all pack sizes may be marketed.

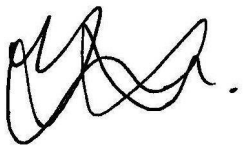
Legal category

To be completed nationally

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

FOR ANIMAL TREATMENT ONLY



Approved: 10 February 2023