SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tauramox 5 mg/ml Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Moxidectin	5 mg	

Excipient(s):

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on Solution
A translucent, colourless to pale yellow slightly viscous solution

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

Infections of cattle with parasites sensitive to moxidectin. For the treatment of infections 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.

4.3 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.

4.4 Special warnings for each target species

For cutaneous application 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).
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.
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.
Do not apply to areas of skin that are contaminated with mud or manure.

4.5 Special precautions for use

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; 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.'

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Moxidectin has been shown to be safe in pregnant and lactating animals and breeding bulls.

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

For pour-on use.
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.
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- and over-dosing.
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.

4.10 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.

4.11 Withdrawal period(s)

Cattle: Meat and offal - 14 days.
Milk - 6 days (144 hours).

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, macrocyclic lactones, milbemycins.
ATCvet Code: QP 54AB02

5.1 Pharmacodynamic properties

Moxidectin is a parasiticide active against a wide range of important internal and external parasites. It is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interference with the GABA (gamma amino butyric acid) receptors involved with neuromuscular transmission.
Moxidectin stimulates the release of GABA and increases its binding to the postsynaptic receptors. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug.

5.2 Pharmacokinetic particulars

Following pour-on application, the drug is distributed throughout the body tissues (except muscle) but due to its lipophilicity the concentrations in fat are 5-15 times those in other tissues.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces, where the parent compound accounts for approximately 50%.

5.3 Environmental properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Alcohol
Polybutene
PPG-2 Myristyl Ether Propionate
Tertiary Butylhydroquinone (E319)
Butylhydroxyanisole (E320)
Citric Acid, Anhydrous
Propylene Glycol
Triglycerides, Medium-chain

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Store in original container.
Protect from light.

6.5 Nature and composition of immediate packaging

The product will be supplied in:

250mL and 1L fluorinated high density polyethylene single neck dispensers with high density polyethylene/polypropylene caps and green fluorinated high density polyethylene ball plugs.
1L, 2.5L and 5L white fluorinated flat high density polyethylene back-packs with white polypropylene easy peel caps.
10L white high density polyethylene fluorinated jerry can with white high density polyethylene cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

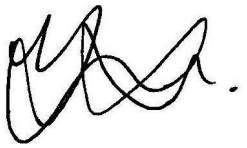
Vm 02000/4406

9. DATE OF FIRST AUTHORISATION

22 March 2018

10. DATE OF REVISION OF THE TEXT

February 2023



Approved: 10 February 2023