1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taurador 5 mg/ml Pour-on Solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Doramectin 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Brilliant blue FCF (E133)	0.007 mg
Cetearyl Octanoate	
Isopropyl alcohol	
Purified Water	
Trolamine	

A pale blue, clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly 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 medicinal product protects cattle against infection or re-infection with the following parasites for the periods indicated.

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

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

3.3 Contraindications

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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 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 veterinary medicinal product, or lack of calibration of a dosing device (if any).

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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.

Avermectins may not be well tolerated in all 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 tortoises). Care should be taken to avoid ingestion of spilled veterinary medicinal 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 medicinal 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:

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Do not smoke or eat while handling the veterinary medicinal product. Wash hands after use. The veterinary medicinal product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons. Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal product. Protective clothing should be washed after use.
In case of accidental spillage onto skin, wash the affected area immediately with soap and water. In case of accidental eye exposure, flush the eyes immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Use only in well-ventilated areas or outdoors.
Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

Special precautions for the protection of the environment:

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments. The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of doramectin (and veterinary medicinal products of the same anthelmintic class) in cattle and sheep. The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

3.6 Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Application site lesion[1]

[1] Small.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days prior to calving.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.

The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

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

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**					
		250 ml	**1 litres**	**2.5 litres**	**5 litres**	**10 litres**	**20 litres**
100 kg	10 ml	25	100	250	500	1000	2000
150 kg	15 ml	16	66	166	333	666	1333
200 kg	20 ml	12	50	125	250	500	1000
250 kg	25 ml	10	40	100	200	400	800
300 kg	30 ml	8	33	83	166	333	666
350 kg	35 ml	7	28	71	142	285	571
400 kg	40 ml	6	25	62	125	250	500
450 kg	45 ml	5	22	55	111	222	444
500 kg	50 ml	5	20	50	100	200	400
550 kg	55 ml	4	18	45	90	181	363
600 kg	60 ml	4	16	41	83	166	333

* Dose rate 1 ml per 10 kg bodyweight

To ensure a correct dosage, 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 bodyweight and dosed accordingly, in order to avoid under- and over- dosing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdoses up to 5 times the label recommended dose resulted in no clinical signs that could be attributed to treatment with doramectin.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 35 days.

Not authorised for use in 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP54AA03

4.2 Pharmacodynamics

Doramectin is a fermentation-derived antiparasitic agent, which belongs to the avermectin class, and is closely related structurally to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods. Whilst it is not possible to assign a single mode of action to the avermectins, it is likely that the entire series share a common mechanism. In parasitic organisms the effect is mediated through a specific avermectin-binding site. The physiological response to avermectin binding is an increase in membrane permeability to chloride ions. In invertebrate nervous tissue an influx of chloride ions into the excitatory motor neurone in nematodes or muscle cell of arthropods results in hyperpolarisation and the elimination of signal transmission with resulting paralysis.

4.3 Pharmacokinetics

Maximum plasma concentration of doramectin occurs in cattle approximately 9 days after topical administration of the veterinary medicinal product. An (apparent) elimination half-life of around 10 days results in sustained doramectin concentrations, which protect animals from parasitic infection and re-infection for extended periods following treatment.

Environmental properties

Doramectin is very toxic to 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Protect from light.
Do not refrigerate.
Store in the original container. Keep the container tightly closed.
Avoid introduction of contamination.
Keep out of the sight and reach of children.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in:

- 250 ml and 1 L standard high density polyethylene bottles with 28 mm polypropylene/high density polyethylene caps.

- 1 L, 2.5 L and 5 L white flat bottomed heavy duty high density polyethylene back-packs with 38mm white polypropylene easy peel caps.

- 10 L and 20 L white high density polyethylene Jerry cans with high density polyethylene caps.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as doramectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/111/001

8. DATE OF FIRST AUTHORISATION

29/11/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12/12/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).