

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {250ml, 1L, 2.5L, 5L}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Taurador 5 mg/ml Pour-on Solution for Cattle

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Doramectin            5 mg

**3. PACKAGE SIZE**

250 mL

1L

2.5L

5L

10 L

20 L

**4. TARGET SPECIES**

Cattle

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

**Administration:**

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 (5mg of doramectin) per 10 kg bodyweight (based on a recommended dosage level of 500 µg doramectin per kg bodyweight).

<b>DOSING GUIDE</b>		<b>ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*</b>					
<b>BODYWEIGHT</b>	<b>DOSE PER ANIMAL</b>	<b>NUMBER OF FULL DOSES PER PACK</b>					
		<b>250ml</b>	<b>1 litre</b>	<b>2.5 litre</b>	<b>5 litre</b>	<b>10 litre</b>	<b>20 litre</b>
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 a correct dosage, body weight should be determined as accurately as possible. Accuracy of the dosing device should be checked.

## 7. WITHDRAWAL PERIODS

Withdrawal period:

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.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

## 9. SPECIAL STORAGE PRECAUTIONS

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.  
Highly flammable – keep away from heat, sparks, open flame or other sources of ignition.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Ltd

**14. MARKETING AUTHORISATION NUMBERS**

Vm: 02000/4358

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL -250ml, 1L,  
2.5L, 5L, (BASE LABEL FOR EXPANDING LABEL - 10L, 20L)}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Taurador 5 mg/ml Pour-on Solution for Cattle

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Doramectin: 5 mg

**3. TARGET SPECIES**

Cattle

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

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.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 3 months.

**7. SPECIAL STORAGE PRECAUTIONS**

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.

Highly flammable – keep away from heat, sparks, open flame or other sources of ignition.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Ltd

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET: 250ml, 1L, 2.5L, 5L**

**PARTICULARS TO APPEAR ON THE EXPANDING LABEL: 10L AND 20L}**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Taurador 5 mg/ml Pour-on Solution for Cattle

**2. Composition**

Each ml contains:

Doramectin: 5 mg

Brilliant blue FCF (E133): 0.007 mg

A pale blue, clear pour-on solution.

**3. Target species**

Cattle

**4. Indications for use**

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*<sup>1</sup>

*Haemonchus placei*

*Trichostrongylus axei*

*T. colubriformis*

*Cooperia oncophora*

*C. punctata*<sup>1</sup>

*C. surnabada*<sup>1</sup> (syn. *mcmasteri*)

*Bunostomum phlebotomum*<sup>1</sup>

*Oesophagostomum radiatum*

*Trichuris* spp.<sup>1</sup>

<sup>1</sup> 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.

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

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

## **5. 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 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 or to any of the excipients.

## **6. Special warnings**

### 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.

### Special precautions for safe use in the target species:

Resistance to doramectin and other avermectins has been reported in gastro-intestinal nematodes, especially *Cooperia oncophora* 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 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 chelonian (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. 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 veterinary medicinal 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.

Pregnancy and lactation:

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

Overdose:

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

## 7. Adverse events

Cattle:

Rare  (1 to 10 animals / 10,000 animals treated):	Application site lesion <sup>1</sup>
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<sup>1</sup> Small.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

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 (5mg of doramectin) per 10 kg bodyweight (based on a recommended dosage level of 500 µg doramectin per kg bodyweight).

<b>DOSING GUIDE</b>		<b>ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*</b>					
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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

## **9. Advice on correct administration**

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 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.

## **11. Special storage precautions**

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.

Shelf life after first opening the immediate packaging: 3 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or label after Exp. The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

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

This veterinary medicinal product should not enter water courses as doramectin is extremely dangerous to 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 02000/4358

The veterinary product will be supplied in:

- 250 ml and 1 L standard high density polyethylene bottles with 28 mm polypropylene/high density polyethylene caps for use with dosing cups.
- 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 for use with a dosing gun delivery system.
- 10 L and 20 L white high density polyethylene Jerry cans with high density polyethylene caps for use with a dosing gun delivery system.

## **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## 16. Contact details

### Marketing authorisation holder and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
Co. Down, BT35 6JP  
Northern Ireland  
Tel: +44 (0)28 3026 4435  
E-mail: [phvdept@norbrook.co.uk](mailto:phvdept@norbrook.co.uk)

### Manufacturer responsible for batch release:

Norbrook Laboratories Limited  
Station Works  
Newry  
Co. Down, BT35 6JP  
Northern Ireland

Norbrook Manufacturing Ltd.  
Rossmore Industrial Estate  
Monaghan  
Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## 17. Other information

For animal treatment only.

### Legal category

POM-VPS

*Gavin Hall*  
Approved: 30 March 2026