SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taurador 10 mg/ml Solution for Injection for Cattle & Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Doramectin 10.00 mg

Excipients:

Qualitative composition of excipients and other constituents
Ethyl oleate
Sesame oil, refined

Clear, colourless to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and Sheep.

3.2 Indications for use for each target species

CATTLE:
For treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice and mange mites.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited larvae)
*O. lyrata**
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
*C. pectinata**
C. punctata
C. surnabada (syn. mcmasteri)
*Nematodirus spathiger**
*Bunostomum phlebotomum**

*Strongyloides papillosus**
Oesophagostomum radiatum
Trichuris spp.*
* adults

Lungworms: (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms: (adults)
Thelazia spp.

Warbles: (parasitic stages)
Hypoderma bovis
H. lineatum

Sucking lice:
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Mange mites:
Psoroptes bovis
Sarcoptes scabiei

May also be used as an aid in the control of *Nematodirus helvetianus*, biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis*.

The pharmacokinetics of this veterinary medicinal product allows protection of cattle against infection or re-infection with the following parasites for the period indicated:

Species	**Days**
Ostertagia ostertagi	35
Cooperia oncophora	21
Dictyocaulus viviparus	35
Bunostomum phlebotomum	22
Oesophagostomum radiatum	21
Trichostrongylus axei	28
Linognathus vituli	28
Psoroptes bovis	42
Haemonchus placei	28

SHEEP:
For treatment and control of *Psoroptes ovis* (sheep scab mite) and for the treatment and control of gastrointestinal roundworms and nasal bots.

Mange mites
Psoroptes ovis

Gastrointestinal roundworms (Adults and fourth stage larvae (L4) unless otherwise indicated):

Chabertia ovina (adults only)
Cooperia curticei (L4 only)
C. oncophora
Gaigeria pachycelis
Haemonchus contortus
Nematodirus battus (L4 only)[1]
Ostertagia (Teladorsagia) circumcincta *
Oesophagostomum columbianum
Strongyloides papillosus
Trichostrongylus axei
Trichostrongylus colubriformis
Trichostrongylus vitrinus
Trichuris spp (Adults only)

* Inhibited larval stages (L_4) including strains that are benzimidazole resistant, are also controlled.

[1] For effective treatment and control of both adults and L4 larvae of *Nematodirus battus* a dose rate of 300 mcg/kg is required.

Lungworms
Dictyocaulus filaria (Adults only)

Nasal bots (1st, 2nd and 3rd instar larvae)
Oestrus ovis

3.3 Contraindications

Do not use in dogs, as severe adverse reactions may occur. In common with other avermectins, certain breeds of dogs, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product.

Do not use in chelonians (e.g. turtles and tortoises). Use of avermectins in these species can lead to death.

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

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection/infestation based on its epidemiological features, for each individual herd/flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

In the absence of risk of co-infection, a narrow spectrum product should be used where available.

Resistance to doramectin and other avermectins has been reported in *Psoroptes ovis* in cattle (Europe) and sheep (UK) and in gastro-intestinal nematodes, especially *Haemonchus spp* (outside Europe/UK)., *Cooperia spp*. and *Ostertagia ostertagi* in cattle (Europe including the UK) and *Teladorsagia spp*., *Trichostrongylus spp*. and *Haemonchus spp*. in sheep (Europe including the UK).

The use of this product should take into account local information about susceptibility of the target parasites, where available.

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).

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (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.
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product does not contain an antimicrobial preservative.
Swab septum before removing each dose.
Use sterile equipment and follow aseptic procedures.
When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus.
For the treatment of individual sheep, a disposable 2 ml syringe calibrated in increments of 0.1 ml should be used.
In young lambs of less than 16 kg bodyweight seek veterinary advice regarding the use of appropriately sized needles and of 1 ml disposable syringes graduated in increments of 0.1 ml or less.

Syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper.
100 ml: The veterinary medicinal product is to be administered using a draw-off needle.
250 ml and 500ml: Vial stoppers must not be broached more than 10 times with an 18G needle.

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

Take care to avoid accidental self-administration. If any adverse effects are noticed following accidental self-administration, seek medical advice and show the package leaflet or the label to the physician.
This veterinary medicinal product can be irritating to eyes. Avoid accidental contact with the eyes, including hand-to-eye contact. In the case of accidental contact with the eyes rinse with plenty of water.
The veterinary medicinal product may cause embryotoxicity and toxic effects to newborns via breastfeeding. Pregnant and breastfeeding women should therefore take special care when handling this veterinary medicinal product.
Do not eat, drink or smoke while handling the product.
Wash hands after use.

Advice to medical practitioners: In case of accidental self-injection specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

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 products of the same anthelmintic class) in cattle and sheep.

The risk to aquatic ecosystems will be reduced by keeping treated cattle away from water bodies for five weeks after treatment.

3.6 Adverse events

None known.

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 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:

May be used in pregnant cows and ewes.

Do not use in pregnant cows or heifers, which are intended to produce milk for human consumption, within 2 months of expected parturition.

Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition.

For more information on use during pregnancy and lactation, see also 'Withdrawal periods' (section 3.12).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Underdosing could result in ineffective use and may favour resistance development.

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

In cattle: A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered in the region of the neck by subcutaneous injection.

In sheep: A single treatment of 1 ml (10 mg doramectin) per 33 kg bodyweight, equivalent to 300 µg/kg bodyweight, administered by intramuscular injection for the treatment and control of *Psoroptes ovis* (sheep scab mite) and adult *Nematodirus battus*. In addition, adequate bio-security measures should be implemented to prevent re-infestation. Ensure that all sheep which have been in contact with infested sheep are treated. After treatment, contact between treated infected and untreated uninfected flocks must be avoided for at least 14 days. A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered by intramuscular injection for the control of certain other gastro-intestinal nematodes and nasal bots.

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

In cattle (SC route only) and sheep (IM route only) overdoses up to 25 and 10 times the maximum label recommended dose respectively, resulted in no adverse clinical signs.

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

CATTLE:
Meat and offal: 70 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 of expected parturition.

SHEEP:
Meat and offal: 70 days
Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP 54AA03

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 cells of arthropods results in hyperpolarisation and the elimination of signal transmission with resulting paralysis. Doramectin is exceptionally well-tolerated in mammals, where receptor/channel complexes are localised in the CNS. Poor penetration of large molecular weight compounds, such as avermectins, through the blood-brain barrier suggests that high systemic concentrations would be required before neurological function is affected.

4.3 Pharmacokinetics

Maximum plasma concentration of doramectin occurs in cattle 3 days after subcutaneous administration of the veterinary medicinal product. In sheep the maximum plasma concentration of doramectin occurs 2 days after intramuscular administration of the veterinary medicinal product. An elimination half-life of around 6 days for cattle, by the subcutaneous route, and 4.5 days for sheep, by the intramuscular route, results in sustained doramectin concentrations which protect

cattle and sheep from parasitic infection and re-infection for extended periods following treatment.

Environmental properties
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.

Doramectin is very toxic to aquatic organisms and may accumulate in sediments.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging:
100 ml: use immediately. Discard any unused material after first opening the primary packaging;
250 ml and 500 ml: 6 months.

5.3 Special precautions for storage

Do not store above 30°C
Do not refrigerate or freeze
Protect from direct sunlight
Store in the original package.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in 100 ml, 250 ml and 500 ml multi-dose Type II amber glass vials with nitryl rubber bungs and aluminium seals.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

This 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 applicable national collection systems.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

7. MARKETING AUTHORISATION NUMBERS

Vm 02000/3008
Vm 02000/5016

8. DATE OF FIRST AUTHORISATION

13 February 2025

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

January 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 28 January 2026
Gavin Hall