Summary of Product Characteristics

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 substance:
Doramectin 5 mg
Excipient(s):
Brilliant blue FCF (E133) 0.007 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on Solution
A pale blue, clear solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the 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 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 product also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

4.3 Contraindications

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities, may occur. See section 4.5 i.

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

4.4 Special warnings for each target species

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

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 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.

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.

4.5 Special precautions for use

i. Special precautions for use in animals.

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 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 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.

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

Persons with known hypersensitivity to the active substance should avoid contact with the product. Do not smoke or eat while handling the product. Wash hands after use. The veterinary product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons. Operators should wear 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 accidental eye exposure occurs, flush the eyes immediately with water and get medical attention. Use only in well ventilated areas or outdoors.

Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

iii. Other precautions

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 further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

4.6 Adverse reactions (frequency and seriousness)

In rare cases (more than 1 but less than 10 animals in 10,000 animals treated) small skin lesions may occur at the administration site.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For topical use: pour-on application
A single treatment of 500 µg of doramectin/kg bodyweight equivalent to 1 ml of product 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.

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

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

4.11 Withdrawal period(s)

Meat and offal: 35 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 (60 days) of expected parturition.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic Products Insecticides and Repellents/Endectocides
ATCvet Code: QP 54AA03

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Maximum plasma concentration of doramectin occurs in cattle approximately 9 days after topical administration of the veterinary 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.

5.3 Environmental properties

Doramectin is very toxic to aquatic organisms.
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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant blue FCF (E133)
Cetearyl Octanoate
Isopropyl alcohol
Purified Water
Trolamine

6.2 Major incompatibilities

None known.

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: 3 months.

6.4 Special precautions for storage

Protect from light.
Do not refrigerate.
Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

The veterinary product will be supplied in:

250mL and 1L standard high density polyethylene bottles with 28mm polypropylene/high density polyethylene caps.
1L, 2.5L and 5L white flat bottomed heavy duty high density polyethylene back-packs with 38mm white polypropylene easy peel caps.
10L and 20L white high density polyethylene Jerry cans with high density polyethylene caps.

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

Extremely dangerous for fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/111/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th November 2013
Date of latest renewal: 29th November 2018

10 DATE OF REVISION OF THE TEXT

January 2019