Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin 0.5% w/v Pour-On Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Ivermectin 0.5% w/v

Excipients:
Patent Blue V (E131) dye 0.0005% w/v
Isopropyl alcohol to 100.0% v/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution
A clear, blue solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (beef and non-lactating cattle).

4.2 Indications for use, specifying the target species

Noromectin Pour-On is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice.

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp, *Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Trichuris* spp (adult). Occasionally variable activity may be observed against *H. placei* (L4), *Cooperia* spp, *T. axei* and *T. colubriformis*.

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia rhodesii

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus,

Biting Lice:
Damalinia (bovicola) bovis

Mange mites:
Chorioptes bovis, Sarcoptes scabiei var *bovis*

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance.

4.4 Special warnings for each target species

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Ostertagia ostertagi* in cattle. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special Precautions for use in animals:
To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or in 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 veterinarian on the correct timing of treatment.

Do not treat cattle when their hair or hide is wet. Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy. Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

Ivermectin is not tolerated well in all non target species (cases of intolerance with fatal outcome are reported in dogs - especially Collies and Bobtails and also in turtles/tortoises).

Special Precautions to be taken by the person administering the veterinary medicinal product to animals:
Highly flammable - keep away from heat, sparks, open flame or other sources of ignition.

Noromectin Pour-On may be irritating to human skin and eyes and the user should be careful not to apply it to himself or 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.

In case of accidental ingestion or spillage onto skin seek medical advice immediately and show the package leaflet or the label to the physician.

Do not smoke or eat while handling the product. Wash hands after use. Use only in well ventilated areas or outdoors.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Noromectin Pour-On for cattle can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption (for information on use in lactating animals, see section 4.11).

4.8 Interaction with other medicinal products and other forms of interactions

The effects of GABA agonists are increased by ivermectin.

4.9 Amounts to be administered and administration route

Ivermectin should be administered topically at 500 microgram per kg bodyweight (1 ml per 10 kg bodyweight).

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

It is recommended that calves which are set-stocked in their first season of grazing should be treated 3, 8 and 13 weeks after turn-out, for optimal benefit from the persistent effect of ivermectin. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked. All calves should be included in the program, and no untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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- or over- dosing.

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

In case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

4.11 Withdrawal period(s)

Meat and offal: 28 days
This product should not be used in cattle producing milk for human consumption. The product should not be used in non-lactating dairy cows including pregnant heifers within 60 days of calving

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide

ATC vet code: QP54 AA01

5.1 Pharmacodynamic properties

Ivermectin is a mixture of two partially modified compounds of abamectin belonging to the avermectin family, which are a macrocyclic lactone group of endoctocides. Abamectin is a mixture of two fermentation products of the soil organism *Streptomyces avermitilis*.

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glumamate-gated chloride channels. The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

After administration of the recommended dosage to cattle varying inter-individual ivermectin plasma levels were observed with mean values of C_{max} and t_{max} of 11.26 ng/ml and 97h, respectively.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodamol CAP
Triethanolamine
Patent Blue V Dye
Isopropyl Alcohol

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 12 months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and composition of immediate packaging

Noromectin Pour-On will be supplied in 250 ml and 1.0L single neck, twin-neck and squeeze-measure high density polyethylene dispensers and 2.5 L and 5 L low density polyethylene backpacks.

A 7 L combinationpack consisting of 2 x 1.0 L single neck, twin-neck and squeeze-measure highdensity polyethylene dispensers and 2 x 2.5 L low density polyethylenebackpacks with a dosing gun.

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

Ivermectin is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with the product or used containers. 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)

VPA22664/052/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 March 2000
Date of last renewal: 28 June 2010

10 DATE OF REVISION OF THE TEXT

November 2019