Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.5 % Pour-On Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ivermectin 0.5 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on Solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (beef and non-lactating cattle).

4.2 Indications for use, specifying the target species

The product is indicated for the 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 dairy cows, during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

4.4 Special warnings for each target species

Assess bodyweight as accurately as possible before calculating the dosage.

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.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.

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.

The product 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.

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

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period, when milk is intended for human consumption. Do not use in 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

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.

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)

Edible tissues: 28 days.

Milk: Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period, when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin in a 22,23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

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 glutamate-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 product, the ivermectin is absorbed through the skin into the circulation of the treated animal. The maximum concentration in plasma occurs

around 97 hours after application. Peak concentrations of about 11.3 ng/ml are obtained.
Elimination is in the faeces (via biliary excretion).

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: 2 years
Shelf-life after first opening of the container: 12 months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and composition of immediate packaging

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

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 product or waste material should be disposed of safely in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate

Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 June 2001
Date of last renewal: 03 September 2006

10 DATE OF REVISION OF THE TEXT

January 2019