Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Macromectin 0.5% w/v Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Ingredient
Ivermectin 0.5 mg

Excipient(s)
Isopropyl alcohol to 1.0ml
Patent Blue V (E131) 0.005mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution
A clear blue liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of the following pathogenic species of parasites of cattle:

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi L4, adult
(including inhibited stage)
Haemonchus placei L4, adult
Trichostrongylus axei L4, adult
T. colubriformis L4, adult
Cooperia spp L4, adult
Oesophagostomum radiatum L4, adult
Strongyloides papillosus adults
Trichuris spp adults

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:

Sarcoptes scabiei var bovis
Chorioptes bovis (reduction of infestation)

Lice:
Linognathus vituli,
Haematopinus eurysternus,
Damalinia bovis

The product given at the recommended dosage of 500 micrograms/kg bodyweight, has persistent activity against *Trichostrongylus axei* and *Cooperia* spp acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also has a persistent activity on horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance.
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 in dogs, may occur.

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 effective 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).

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 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 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.

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. Under such conditions, efficacy of the product against infections of *Ostertagia ostertagi* or *Dictyocaulus viviparous* may be maintained.
Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

Avermectins may not be well tolerated in all non target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breed or crosses, and also in turtles/tortoises.

The influence of extreme climatic conditions on the persistent activity of the product is unknown. As ivermectin is extremely dangerous for fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

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

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.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.
Do not smoke or eat while handling the product.
Keep away from heat, spark, open flame or other sources of ignition.
HIGHLY FLAMMABLE.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, slight irritation at the application site may occur. However, usually, these irritations rapidly disappear without treatment.

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. The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves. (For information on use in lactating animals, see section 4.11).

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 microgram/kg bodyweight). Assess bodyweight as accurately as possible before calculating the dosage.
Administration: The formulation should be applied along the mid-line of the back narrow strip between the withers and tailhead.

To obtain optimal benefit from the product, it is recommended that it be used as part of a treatment programme based on the epidemiology of the parasites in question.

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

No sign of toxicity appeared up to 1000 microgram/kg (2 times the recommended dose rate). No antidote has been identified.
The symptoms of overdose can be trembling, convulsions and coma. In case of overdose, a symptomatic treatment should be given.

4.11 Withdrawal Period(s)

Meat and offal: 28 days

Not permitted for use in lactating cows producing milk for human consumption. Do not use in non lactating dairy cows including pregnant heifers within 60 days prior to calving.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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 parasite. 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 properties

After a single topical administration of 500 microgram per kilogram bodyweight, the mean maximum plasma concentration (Cmax) of 11.26 ng/ml was reached after a mean (Tmax) of 96.8 hours. The concentrations mentioned relate to the main compound of ivermectin, 22, 23-dihydroavermectin B_{1a}. The excretion occurs mainly through faeces and, in a lesser proportion, via urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodamol CAP
Trolamine
Patent Blue V Dye (E131)
Isopropyl Alcohol

6.2 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: 11 months.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

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

6.5 Nature and composition of immediate packaging

The product will be supplied in:

250 ml and 1.0 L single-neck high density polyethylene dispensers
250 ml and 1.0 L twin-neck high density polyethylene dispensers
250 ml and 1.0 L squeeze-measure high density polyethylene dispensers
1 L high density polyethylene backpacks
2.5 L 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface water or ditches. Do not contaminate surface waters or ditches with the product or used container.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10 DATE OF REVISION OF THE TEXT

January 2023