IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/070/001**
Case No: 7003720

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, **Camlough Road**, **Co. Down BT35 6JP**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Levacide Pour-on 200mg/ml

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **11/12/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Pour-on 200mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Levamisole (as lavamisole hydrochloride) 200 mg/ml

Excipients:

Patent Blue (E131) 1 mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on Solution
A dark blue non-aqueous solution for external use.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

Levacide Pour-on is a broad spectrum anthelmintic indicated for use in cattle in the treatment and control of nematode infections such as parasitic gastro-enteritis and lungworm disease caused by the following mature and developing immature gastro-intestinal and pulmonary nematodes :

Lungworms -Dictyocaulus viviparus

Gastro-intestinal worms - Trichostrongylus spp; Cooperia spp; Ostertagia ostertagi (except inhibited O. ostertagi larvae); Haemonchus spp; Nematodirus spp; Bunostomum spp; Oesophagostomum spp.

4.3 Contraindications

Do not use in animals producing milk for human consumption.
Do not use in animals with known hypersensitivity to the active ingredients.

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 body weight, 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 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.

4.5 Special precautions for use

Special precautions for use in animals

Do not treat animals when wet, and where possible, for one hour post treatment, prevent treated animals from being exposed to rain.

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

Do not exceed the stated dose. For external use only.

The bodyweight of animals should be assessed as accurately as possible before calculating the dose.

As with other anthelmintics, veterinary advice should be sought:
(a) on appropriate dosing programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing;
(b) if the product does not achieve the desired effect, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Do not eat, drink or smoke when using this product. Wear rubber gloves and boots and waterproof bib-apron when applying this product. Wash splashes from eyes and skin immediately. Eyes should be irrigated for fifteen minutes using an eyewash bottle to avoid irritation. Remove any contaminated clothing immediately. Wash hands and exposed skin after handling this product, and before meals. Use in a well ventilated area.

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using this product or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Local skin reactions at the site of administration may be observed occasionally. These may be characterised by subcutaneous oedema and epidermal flaking. Some sloughing of epidermal layers may be seen in severe cases. Symptomatic treatment should be provided where necessary. Lesions tend to resolve over a few weeks.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant and lactating animals.

Do not use in animals producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

4.9 Amounts to be administered and administration route

Levacide Pour-on is indicated for external transcutaneous administration to cattle.

The recommended dose rate is 10 mg levamisole/kg bodyweight equivalent to 2.5 ml per 50 kg bodyweight.

Bodyweight	**Dose**
Up to 50 kg (1 cwt)	2.5 ml
51 - 100 kg (1-2 cwt)	5.0 ml
101 - 150 kg (2-3 cwt)	7.5 ml
151 - 200 kg (3-4 cwt)	10.0 ml
201 - 250 kg (4-5 cwt)	12.5 ml
251 - 300 kg (5-6 cwt)	15.0 ml
301 - 350 kg (6-7 cwt)	17.5 ml

Above 350 kg give a further 2.5 ml for each additional 50 kg bodyweight.

For external administration only. Apply along the flattest part of the backline at the rate of 10 mg levamisole/kg bodyweight, equivalent to 2.5 ml per 50 kg bodyweight.

For 250 ml, 500 ml and 1L twin neck dispensers, simply squeeze the bottle to allow the appropriate amount of liquid into the calibrated dispenser. Let it "pool" on the flattest part of the animals back. The 2.5 L "back-pack" or "Jerry-can" should be used in conjunction with an appropriate gun.

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 overdosing.

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

In cases of overdosage, hyperaesthesia, tremor and occasionally diarrhoea may occur.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 21 days from the last treatment. Not for use in cows producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Imidazothiazoles

ATCvet Code: QP52AE01

5.1 Pharmacodynamic properties

Levamisole is the *laevo* isomer of tetramisole, a racemic imidazothiazole derivative, and is a member of the imidazothiazole group of anthelmintics.

Levamisole is a broad spectrum anthelmintic which displays excellent activity against mature and developing immature stages of gastro-intestinal and pulmonary nematodes.

By behaving as a cholinergic agonist of the nematode nervous system levamisole mimics the action of the excitatory neurotransmitter, acetylcholine, which results in sustained (spastic) muscle paralysis. By inhibiting fumarate reductase, levamisole also has a minor role to play in disrupting the nematodes energy pathway. However this is of limited consequence in comparison to its role as a paralysing agent.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate
Patent Blue (E131)
Denatonium Benzoate
Isopropyl Alcohol

6.2 Incompatibilities

None.

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: 6 months

6.4 Special precautions for storage

Store below 25ºC. Do not freeze.
Protect from light.
Store in the original container.
Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

Levacide Pour-on will be supplied in 250 ml, 500 ml and 1 L high density polyethylene twin neck dispensers complete with tamper evident caps. The larger 2.5 L fill size will take the form of either “Jerry-cans” or collapsible “back-packs”.

The 2.5 litre “back-pack” or “Jerry-can” should be used in conjunction with an appropriate dosing gun. Use of conventional drenching equipment is not recommended as the product may have a detrimental effect on certain components. If in doubt, consult your supplier.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with product or used containers.

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co Down BT35 6JP
Northern Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/070/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th December 2007

10 DATE OF REVISION OF THE TEXT