1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Pour-on 200 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Levamisole (as levamisole hydrochloride) 200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue (E131)	1 mg
Isopropyl Myristate	
Denatonium Benzoate	
Isopropyl Alcohol	

A dark blue non-aqueous solution for external use.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product 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.

3.3 Contraindications

Do not use in animals producing milk for human consumption.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary 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, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Target species: Cattle.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Localised skin reaction (e.g., skin oedema, flaking skin), Local skin slough[1]

[1] In severe cases sloughing of the epidermal layer. Symptomatic treatment should be provided where necessary. Lesions tend to resolve over a few weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation

holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactations.

Do not use in animals producing milk for human consumption.

3.8 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.

3.9 Administration routes and dosage

The veterinary medicinal product 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 "Jerrycan" 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 21 days.

Animals must not be slaughtered for human consumption during treatment.

Not authorised for use in cows producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AE01

4.2 Pharmacodynamics

The veterinary medicinal product is the *laevo* isomer of tetramisole, a racemic imidazothiazole derivative, and is a member of the imidazothiazole group of anthelmintics.

The veterinary medicinal product 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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 “backpacks”.

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.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22664/047/001

8. DATE OF FIRST AUTHORISATION

12 December 1997

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

02 October 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).