1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Injection 75 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Levamisole (as levamisole hydrochloride) 75 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate (E218)	1.5 mg
Sodium Metabisulphite	1.5 mg
Sodium Citrate	
Citric Acid Anhydrous	
Disodium Edetate	
Quinoline Yellow (E104)	
Water for Injection	

A clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is a broad spectrum anthelmintic for use in the treatment and control of nematode infections. It should be used in cases of parasitic gastro-enteritis and lungworm disease caused by mature and developing immature forms of those organisms sensitive to treatment with Levamisole Hydrochloride including the following:

Lungworms (adult and larval stages): *Dictyocaulus* spp.

Gastro-intestinal worms (adult and larval stages):
Trichostrongylus spp.
Cooperia spp.
Ostertagia spp. (except inhibited *Ostertagia* larvae in cattle)
Haemonchus spp.
Nematodirus spp.
Bunostomum spp.
Oesophagostomum spp.
Chabertia spp.

3.3 Contraindications

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 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

After treatment animals should be moved to clean pasture in order to prevent re-infection. Where this is not done, further dosing at 21 day intervals may be necessary.

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

When using, do not eat, drink or smoke.
Wash hands and exposed skin before meals and after work.
Wash splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
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 the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Cattle and sheep.

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction[1]

[1] Normally non-irritant and should resolve naturally in a short period of time.

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 its local representative 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 lactation.
However, care should be taken to avoid unnecessary stress when handling heavily pregnant animals.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent treatment with products containing organophosphorus compounds or diethylcarbamazine citrate should be avoided. These compounds should not be administered within a period of 14 days before or after treatment with Levamisole. Levamisole is not affected by benzimidazole resistance.

3.9 Administration routes and dosage

The veterinary medicinal product should be administered by subcutaneous injection at a rate of 7.5 mg Levamisole hydrochloride per kg bodyweight (1 ml/10 kg bodyweight).

To ensure administration of a correct dose, bodyweight 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 overdosing. Use properly calibrated dosing equipment. Do not exceed more than one broach per vial. The veterinary medicinal product is recommended to be administered using a draw-off needle.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

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

The veterinary medicinal product is safe for use in cattle and sheep at the recommended dosages. However, if recommended doses are exceeded animals may exhibit signs of impaired motor function such as muscle tremors and increased salivation, which are of a temporary nature.

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: 14 days.

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

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QP52AE01

4.2 Pharmacodynamics Levamisole Hydrochloride is the levo isomer of dl 2, 3, 5, 6-Tetrahydro-6-phenyl-imidazo (2,l-b) thiazole Hydrochloride. Levamisole was found to be active against adult and immature gastro-intestinal and pulmonary nematodes when administered to experimentally

infected animals by the oral, subcutaneous, intramuscular or intraperitoneal routes. It is thought to act by paralysing the susceptible parasites which are then expelled from the alimentary canal.

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: use immediately.

5.3 Special precautions for storage

Do not store above 25ºC.
Store in the original package, in an upright position.
Protect from light.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in glass vials in a cardboard box, sealed with bromobutyl bung and aluminium seals.

Package size:

1 x 100 ml vial in a cardboard box
1 x 250 ml vial in a cardboard box
1 x 500 ml vial in a cardboard box
6 x 500 ml vials with 1 protective container in a cardboard box.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22664/025/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

02/03/2026

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).