1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Low Volume Worm Drench 75 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
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
Tartrazine (E102)	0.11 mg
Sodium Metabisulphite	1.5 mg
Disodium Edetate	
Sodium Citrate	
Citric Acid Anhydrous	
Purified Water	

A yellow viscous 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.

Lungworms:
Dictyocaulus spp.

Gastrointestinal worms:
Trichostrongylus spp.
Cooperia spp.
Ostertagia spp. (except inhibited *Ostertagia* larvae)
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. Do not use in animals producing milk for human consumption.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Care should be taken when treating heavily pregnant animals or animals under stress from adverse weather conditions, poor nutrition, penning, handling etc. The veterinary medicinal product is not effective against Type II Ostertagiasis (winter scours) in cattle. In cases of lungworm infections, coughing may persist for a considerable time following successful treatment with the veterinary medicinal product. This is due to tissue damage caused by the parasites.

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.

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 splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
Wash hands and exposed skin before meals and after work.
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, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 lactation.

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.

3.9 Administration routes and dosage

Administer as an oral drench using a dosing gun system at a rate of 7.5 mg levamisole hydrochloride per kg bodyweight or 1 ml of the veterinary medicinal product/ 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.

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)

If recommended doses are exceeded animals may exhibit signs of impaired motor functions 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 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 (2,1-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

5.3 Special precautions for storage

Store below 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

500 ml, 1 litre and 2.5 litre multidose polyethylene containers sealed with a plastic screw top and plastic coated paper washers for 1 litre and 2.5 litre packs and nitryl bungs for the 500 ml packs.

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 22664/026/001

8. DATE OF FIRST AUTHORISATION

01 October 1989

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

20 August 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).