# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 7.5% Solution for Injection for Cattle and Sheep.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance:**

Levamisole Hydrochloride 7.5% w/v

**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, free from visible particles.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle and sheep.

### 3.2 Indications for use for each target species

A broad spectrum anthelmintic for use in the treatment and control of nematode infections. The veterinary medicinal product 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 (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

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

## 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 (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.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

Care should be taken to estimate accurately the liveweight of animals to be treated. After treatment animals should be moved to clean pasture in order to prevent re-infection.

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 clinical effect since other diseases, nutritional disturbances or anthelmintic resistance might be involved.

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.
Care should be taken to avoid accidental self-injection: may cause irritation at site of injection. Wash splashes from eyes and skin immediately. If irritation persist, seek medical advice and show the package leaflet or the label to the physician. Remove any contaminated clothing immediately. Wash hands and exposed skin after handling this product and before meals. 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 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 and sheep.

| | |
|---|---|
| Very rare<br>(<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 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:

The veterinary medicinal product can be safely administered to pregnant or lactating animals.
However care should be taken when treating heavily pregnant animals and animals under stress from adverse weather conditions, poor nutrition, penning, handling etc.

## 3.8 Interaction with other medicinal products and other forms of interaction

Levamisole activity 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 per kg bodyweight. Usual aseptic precautions should be observed. Cattle should be dosed at a rate of 1 ml of product per 10 kg bodyweight and sheep at a rate of 0.5 ml per 5 kg bodyweight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. The veterinary medicinal product is to be administered using a draw off needle.
Divide large doses between two or more injection sites.
Do not mix with any other products before administration except if premixing is done by a veterinary surgeon or a pharmacist.

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

Levacide Injection 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 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

Cattle
Meat and offal: 28 days

Sheep
Meat and offal: 15 days

Not authorised for use in cattle and sheep producing milk for human consumption.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:
QP52AE01

### 4.2 Pharmacodynamics

Levamisole hydrochloride is the laevo 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.
Shelf life after first opening the immediate packaging: use immediately.

### 5.3 Special precautions for storage

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

In order to minimise the risk of infection, needles should be changed as frequently as possible.
Following withdrawal of the first dose, use the product immediately.
Discard any unused material after first opening the primary packaging

### 5.4 Nature and composition of immediate packaging

Glass vials with bromobutyl bung closures and aluminium seals containing
1x100 ml vial,
1x 250 ml vial,
1x 500 ml vial

Protective plastic container with 5x 500 ml vials.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product 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 Limited

## 7. MARKETING AUTHORISATION NUMBER

Vm 02000/4049

## 8. DATE OF FIRST AUTHORISATION

27 April 1983

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

December 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

*Gavin Hall*
Approved: 27 March 2026