

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 7.5% Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Levamisole (as levamisole hydrochloride) 7.5 % w/v

3. PACKAGE SIZE

100 ml,
250 ml,
500 ml.
6 x 500 ml

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

The veterinary medicinal product should be administered by subcutaneous injection at a rate of 7.5 mg levamisole hydrochloride per kg bodyweight. Usual aseptic precautions should be observed. The veterinary medicinal product is to be administered using a draw-off needle.

Dosage Guide:

CATTLE: 1 ml per 10 kg bodyweight

Bodyweight	Dose
50 kg (approx 1 cwt)	5 ml
100 kg (approx 2 cwt)	10 ml
150 kg (approx 3 cwt)	15 ml
200 kg (approx 4 cwt)	20 ml
250 kg (approx 5 cwt)	25 ml
300 kg (approx 6 cwt)	30 ml

Cattle over 300 kg should be given a further 1 ml per additional 10 kg bodyweight

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.

SHEEP: 0.5 ml per 5 kg bodyweight

Bodyweight	Dose
10 kg (approx 22 lb)	1 ml
20 kg (approx 44 lb)	2 ml
30 kg (approx 66 lb)	3 ml
40 kg (approx 88 lb)	4 ml
50 kg (approx 110 lb)	5 ml
60 kg (approx 132 lb)	6 ml

Sheep over 60 kg should be given a further 0.5 ml per additional 5 kg bodyweight

7. 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Store in the original package, in an upright position.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

14. MARKETING AUTHORISATION NUMBERS

Vm 02000/4049

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 7.5% Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Levamisole (as levamisole hydrochloride) 7.5% w/v

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Subcutaneous injection.
Read the package leaflet before use.

5. 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.

6. EXPIRY DATE

Exp.:

Exp. {mm/yyyy}

Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Levacide 7.5% Solution for Injection for cattle and sheep.

2. Composition

Levamisole (as levamisole hydrochloride) 7.5 % w/v.

3. Target species

Cattle and sheep.

4. Indications for use

Levacide Injection is a broad spectrum anthelmintic for use in the treatment and control of nematode infections in cattle and sheep. Levacide Injection should be used in cases of parasitic gastroenteritis and lungworm 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 in cattle)

Haemonchus

Nematodirus spp

Bunostomum spp

Oesophagostomum spp

Chabertia spp

5. Contraindications

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

6. Special warnings

Special warnings:

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

Although normally non-irritant, the veterinary medicinal product may occasionally cause local reaction at the site of the injection; this should resolve naturally in a short period of time.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

The product may be administered to pregnant or lactating animals but care should be taken when treating heavily pregnant animals or animals suffering stress from adverse weather conditions, poor nutrition, penning, handling, etc.

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

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing.

Veterinary advice should be sought if the product does not achieve the desired clinical effect since other diseases, nutritional disturbances or anthelmintic resistance might be involved.

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. After treatment animals should be moved to clean pasture in order to prevent re-infection.

Levamisole activity is not affected by benzimidazole resistance.

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.

Resistance to levamisole has been reported in *Teladorsagia*, *Cooperia* and *Trichostrongylus* species in sheep in a number of countries, including the EU. There are reports of resistance in *Haemonchus* in sheep outside the EU. Resistance to levamisole has been reported in *Teladorsagia* species in cattle in developed countries such as New Zealand. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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 persists, 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.

7. Adverse events

Target species: Cattle and sheep.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction ¹
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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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Levacide Injection should be administered by subcutaneous injection at a rate of 7.5 mg levamisole hydrochloride per kg bodyweight. Usual aseptic precautions should be observed.

Dosage Guide:

CATTLE: 1 ml per 10 kg bodyweight

Bodyweight	Dose
50 kg (approx 1 cwt)	5 ml
100 kg (approx 2 cwt)	10 ml
150 kg (approx 3 cwt)	15 ml
200 kg (approx 4 cwt)	20 ml
250 kg (approx 5 cwt)	25 ml
300 kg (approx 6 cwt)	30 ml

Cattle over 300 kg should be given a further 1 ml per additional 10 kg bodyweight.

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.

SHEEP: 0.5 ml per 5 kg bodyweight

Bodyweight	Dose
10 kg (approx 22 lb)	1 ml
20 kg (approx 44 lb)	2 ml
30 kg (approx 66 lb)	3 ml
40 kg (approx 88 lb)	4 ml
50 kg (approx 110 lb)	5 ml
60 kg (approx 132 lb)	6 ml

Sheep over 60 kg should be given a further 0.5 ml per additional 5 kg bodyweight. If excessive broaching's are required, the use of a draw off needle is recommended.

9. Advice on correct administration

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.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in the original package, in an upright position.

Protect from light.

Keep the container in the outer carton.

Shelf life after first opening the immediate packaging: use immediately.

Discard any unused material after first opening the primary packaging.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton...after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

To be supplied only on veterinary prescription.

For animal treatment only

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/4049

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

Package size:

1x 100 ml vial in a cardboard box

1x 250 ml vial in a cardboard box

1x 500 ml vial in a cardboard box

1x Protective plastic container and 6 x 500 ml vial in a cardboard box.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down,
BT35 6JP
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

17. Other information

POM-VPS

Chemical group of anthelmintic: 2-LV

Gavin Hall
Approved: 20 April 2026