PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 7.5% Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear yellow aqueous solution, containing 7.5% w/v Levamisole Hydrochloride and 0.15% w/v Methyl Para Hydroxybenzoate as antimicrobial preservative Sodium Metabisulphate 0.15% w/v and Disodium Edetate Dihydrate 0.05% w/v as antioxidents and 0.1% w/v Quinoline Yellow (E104).

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

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 spp
Nematodirus spp
Bunostumum spp
Oesophagostomum spp
Chabertia spp

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Dosage guide:
CATTLE: 1 ml per 1 kg bodyweight

Bodyweight	**Dose**
50 kg (approx. 1cwt)	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 5kg 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.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 28 days from the last treatment.
Sheep may be slaughtered for human consumption only after 15 days from the last treatment.

This product must not be used in cattle and sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Levacide Injection is sage for use in cattle and sheep at the recommended dosages. However, if the recommended dose rates are exceeded, animals may exhibit signs of impair motor function such as muscle tremors, head shaking and increased salivation, which are of a temporary nature. Although normally non-irritant, Levacide Injection 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 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. Following withdrawal of the first dose, use the product within 28 days. In order to minimise the risk of infection, needles should be change frequently. In cases of lungworm infections, coughing may persist for a considerable time following successful treatment with Levacide Injection. 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. When the container is opened for the first time, using the in-use shelf-life which is specified on the package box, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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.
- Under dosing, 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 (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 on *Teladorsagia, Cooperia* and *Trichostrongylus* species on sheep in a number of countries, including 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.

Operator Warnings:

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. 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 medical advice should be sought immediately.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. 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 within 28 days.

Keep container in outer carton.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waster regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-VPS

To be supplied on veterinary prescription

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry, Co. Down, BT35 6JP

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4049

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 7.5% Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

7.5% w/v Levamisole Hydrochloride

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

A clear yellow aqueous solution, containing 7.5% w/v Levamisole Hydrochloride and 0.15% w/v Methyl Para Hydroxybenzoate as antimicrobial preservative Sodium Metabisulphate 0.15% w/v and Disodium Edetate Dihydrate 0.05% w/v as antioxidents and 0.1% w/v Quinoline Yellow (E104).

4. ROUTE(S) OF ADMINISTRATION

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

5. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 28 days from the last treatment.
Sheep may be slaughtered for human consumption only after 15 days from the last treatment.
This product must not be used in cattle and sheep producing milk for human consumption.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufactured by:
Norbrook Laboratories Limited
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Carnbane Industrial Estate
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Co. Down
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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

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Haemonchus spp
Nematodirus spp
Bunostumum spp

Oesophagostomum spp
Chabertia spp

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle and Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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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 medical advice should be sought immediately.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waster regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

POM-VPS

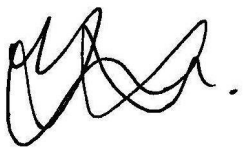
To be supplied on veterinary prescription

For animal treatment only

Keep out of the sight and reach of children

Vm 02000/4049

Package Size
Multidose collapsible polyethylene containers of 100 ml, 250 ml and 500 ml capacity.



Approved: 28 October 2022