Carton Text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEVACIDE LOW VOLUME 7.5% ORAL SOLUTION.
Cattle and Sheep Worm Drench

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Levamisole Hydrochloride 7.5% w/v

3. PHARMACEUTICAL FORM

A clear, yellow solution

4. PACKAGE SIZE

Multidose polyethylene containers of 500 ml, 1 litre and 2.5 litre.

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

Levacide Low Volume is a broad-spectrum anthelmintic for use in the treatment and control of nematode infections in cattle and sheep. Levacide Low Volume 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 in cattle).
Haemonchus spp
Nematodirus spp
Bunostomum spp
Oesophagostomum spp
Chabertia spp

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Levacide Low Volume should be administered as an oral drench. Dosing must be carried out accurately using a dosing gun system at a rate of 7.5 mg levamisole hydrochloride/kg bodyweight.

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)

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)

Do not mix with other products

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 14 days from the last treatment.

Sheep may be slaughtered for human consumption only after 21 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 Low Volume is safe for use in cattle and sheep at the recommended dosages. However, if the recommended dosages are exceeded, animals may exhibit signs of impaired motor functions such as muscle tremors, head shaking and increased salivation which are of a temporary nature.

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

Levacide Low Volume may be 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.

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 Levacide Low Volume. 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.

OPERATOR WARNINGS:

Do not eat, drink or smoke when using this product. 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

D.O.M.:

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.

Keep container in outer carton.

12. SPECIAL 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 waste regulatory authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

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

KEEP OUT OF THE REACH AND SIGHT 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 02000/4081

17. MANUFACTURER'S BATCH NUMBER

B.N.:

LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEVACIDE LOW VOLUME 7.5% ORAL SOLUTION.
Cattle and Sheep Worm Drench

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Levamisole Hydrochloride 7.5% w/v

3. PHARMACEUTICAL FORM

A clear, yellow solution

4. PACKAGE SIZE

500 ml/1L/2.5L

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

Levacide Low Volume is a broad-spectrum anthelmintic for use in the treatment and control of nematode infections in cattle and sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to cattle and sheep at a dose rate of 7.5 mg levamisole hydrochloride/kg bodyweight.

DOSAGE INSTRUCTIONS

CATTLE - 1 ml per 10 kg bodyweight

BODYWEIGHT	**DOSE**
50 kg (approx. 1 cwt)	5 ml
100 kg (approx 2 cwt)	10 ml
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(Cattle over 300 kg, a further 1 ml per additional 10 kg)

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(Sheep over 60 kg, a further 0.5 ml per additional 5 kg)

Do not mix with other products

8. WITHDRAWAL PERIOD

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

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 14 days from the last treatment.

Sheep may be slaughtered for human consumption only after 21 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

NOTE: This is a highly concentrated product.

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

Levamisole activity is not affected by benzimidazole resistance.

FOR ORAL USE ONLY

For Operator Warnings and Further Information: See carton text.

10. EXPIRY DATE

D.O.M.:

Exp:

11. SPECIAL STORAGE CONDITIONS

Protect from light.

Do not store above 25ºC.

Keep container in outer carton.

12. SPECIAL 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 waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

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

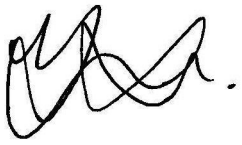
16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4081

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

B.N.:



Approved: 28 October 2022