PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Pour-On solution 20 %w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Levamisole (as levamisole hydrochloride) 20 % w/v.

3. PHARMACEUTICAL FORM

Levacide Pour-On is a blue solution for external pour-on transcutaneous administration.

4. PACKAGE SIZE

500 ml squeeze and pour pack with calibrated dispenser and 2.5 L container. The 2.5 L Jerry-can should be used in conjunction with a standard dosing gun.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Levacide Pour-On is a broad spectrum anthelmintic indicated for external use in cattle in the treatment and control of nematode infections such as parasitic gastro-enteritis and lungworm disease caused by mature and developing immature gastro-intestinal and pulmonary nematodes.

Lungworms:

Dictyocaulus viviparus

Gastrointestinal Roundworms:

Trichostrongylus spp
Cooperia spp
Ostertagia ostertagi (except inhibited *O. ostertagi* larvae)
Haemonchus spp
Nematodirus spp
Bunostomum spp
Oesophagostomum spp

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Levacide Pour-On is indicated for external pour-on transcutaneous administration to cattle.

The recommended dose rate is 10 mg levamisole per kg bodyweight, equivalent to 2.5 ml per 50 kg bodyweight.

The bodyweight of animals should be assessed as accurately as possible before calculating the dosage.

Bodyweight	**Dose**	**No. of Doses per Pack**
Up to 50 kg (1 cwt)	2.5 ml	**200**
51-100 kg (1-2 cwt)	5 ml	**100**
101-150 kg (2-3 cwt)	7.5 ml	**67**
151-200 kg (3-4 cwt)	10 ml	**50**
201-250 kg (4-5 cwt)	12.5 ml	**40**
251-300 kg (5-6 cwt)	15 ml	**33**
301-350 kg (6-7 cwt)	17.5 ml	**29**

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

Above 350 kg give a further 2.5 ml for each additional 50 kg bodyweight.

For external administration only: Pour on from the calibrated dispenser or using a standard dosing gun. Apply along the flattest part of the backline at the rate of 10 mg levamisole/kg bodyweight, equivalent to 2.5 ml per 50 kg bodyweight.

Dosing schedule: Dose all young cattle in early summer and if possible move onto clean pasture. Seek veterinary advice on subsequent retreatment.

Treatment of lungworm infection: Cattle should be dosed on the first signs of lungworm infestation; (rapid breathing or coughing). Seek veterinary advice on subsequent retreatment.

Shake well before use.

Equipment should be thoroughly cleaned before and after dosing.

APPLICATION:

For the 500 ml twin neck dispenser, simply squeeze the bottle to allow the appropriate amount of liquid into the calibrated dispenser. Apply along the backline and let it "pool" on the flattest part of the animal's back. The 2.5 L Jerry-can should be used in conjunction with a standard dosing gun.

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. Do not use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Do not treat animals when wet, and where possible, prevent treated animals from being exposed to rain for one hour post treatment.

Levacide Pour-On is safe for use in cattle at the recommended dosage. In cases of overdose (which only occurs at over five times the recommended dose rate), hyperaesthesia, tremor and occasionally diarrhoea may occur.

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

Do not exceed the stated dose.

The bodyweight of animals should be assessed as accurately as possible before calculating the dose. As with other anthelmintics, 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, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

Levacide Pour-On 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.

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* 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.

Side effects:
At the recommended dose rates, animals should not show any adverse effects. However, local skin irritation at the application site may be observed occasionally, characterised by subcutaneous oedema. Severe cases may show signs of epidermal flaking for which symptomatic treatment is recommended.

Operator Warnings
Highly flammable. Keep away from heat and sources of ignition.

Do not eat, drink or smoke when using this product. Wear rubber gloves, boots and waterproof bib-apron when applying this product. Avoid contact with skin and eyes. In case of accidental skin or eye contact, wash/irrigate splashes from skin and eyes immediately with clean water. If irritation persists seek medical advice. Remove any contaminated clothing immediately. Wash hands and exposed skin after handling this product, and before meals. Use in a well-ventilated area.

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. Do not freeze. Protect from light.

Store tightly closed in original container. Following withdrawal of the first dose, use the product within 6 months. Discard unused material.

Keep container in outer carton.

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 waste regulation authority.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH 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
Station Works
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)

ManA 2000
Vm 02000/4138

17. MANUFACTURER'S BATCH NUMBER

B.N.:

FURTHER INFORMATION:
Levamisole belongs to the Imidazothiazole (2-LM) class of anthelmintics.

In cases of lungworm infection coughing may persist for a considerable time following successful treatment. This is due to tissue damage caused by the parasites.

After dosing animals should be moved to clean pasture. If this is not possible retreatment at regular intervals may be required to prevent re-infection.

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

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,
Station Works,
Newry,
Northern Ireland. BT35 6JP

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Pour-On solution 20 %w/v

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

Levamisole (as levamisole hydrochloride) 20 % w/v.

4. PHARMACEUTICAL FORM

Pour-on solution.

5. PACKAGE SIZE

500 ml / 2.5 litres

6. INDICATION(S)

For the treatment and control of nematode infections such as parasitic gastro-enteritis and lungworm disease caused by mature and developing immature gastro-intestinal and pulmonary roundworms sensitive to levamisole.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cattle

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

For external pour-on transcutaneous administration to cattle. Recommended dose rate is 10 mg levamisole per kg bodyweight, equivalent to 2.5 ml per 50 kg bodyweight.
Pour on from the calibrated dispensers or using a standard dosing gun.
Apply along the flattest part of the backline.

Dosage Guide:
10 mg/kg bodyweight [2.5 ml Levacide Pour-On per 50 kg (1 cwt) bodyweight].

Bodyweight	**Dose**	
Up to 50 kg (1 cwt)	2.5	ml
51-100 kg (1-2 cwt)	5	ml
101-150 kg (2-3 cwt)	7.5	ml
151-200 kg (3-4 cwt)	10	ml
201-250 kg (4-5 cwt)	12.5	ml
251-300 kg (5-6 cwt)	15	ml
301-350 kg (6-7 cwt)	17.5 ml	

Above 350 kg give a further 2.5 ml for each additional 50 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.

11. ADVICE ON CORRECT ADMINISTRATION

12. 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.
Do not use in animals producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not freeze. Protect from light.
Store tightly closed in original container.
Keep container in outer carton.

FLAME SYMBOL

14. SPECIAL WARNING(S)

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.
Do not treat animals when wet, and where possible, for one hour post treatment, prevent treated animals from being exposed to rain. Following withdrawal of the first dose use the product within 6 months. Discard unused product. Do not exceed the stated dose.

Operator Warnings:
Highly flammable. Keep away from heat and sources of ignition.
Do not eat, drink or smoke when using this product. Wear rubber gloves, boots and a waterproof bib-apron when applying the product. Avoid contact with skin and eyes. In case of accidental skin or eye contact, wash/irrigate splashes from skin and eyes immediately with clean water. If irritation persists seek medical advice.

Remove any contaminated clothing immediately.

Wash hands and exposed skin after handling this product and before meals. Use in a well-ventilated area.

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.

For external use only. Further Information: See Carton Text.

15. EXPIRY DATE

D.O.M.:
Exp.:

Discard Date:_____

16. 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.
Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. 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.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

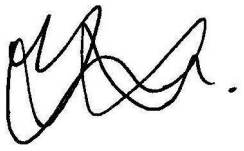
20. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4138

21. MANUFACTURER'S BATCH NUMBER

B.N.:

LOGO



Approved: 28 October 2022