

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Downland Fluke and Worm Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3.0% w/v Levamisole Hydrochloride and

6.0% w/v Oxyclozanide

3. PHARMACEUTICAL FORM

Oral Suspension.

A bright yellow, viscous suspension.

4. PACKAGE SIZE

Multidose low-density polyethylene containers of 1 litre, 2.5 litres and 4 litres.

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

Downland Fluke and Worm Drench is a broad spectrum anthelmintic for use in the treatment and control of both gastro-intestinal and pulmonary nematode and adult liver fluke infections in cattle and sheep only.

Downland Fluke and Worm Drench should be used in cases of parasitic gastroenteritis and lungworm disease caused by mature and developing immature forms of those organisms sensitive to treatment with levamisole hydrochloride.

Lungworms:

Dictyocaulus spp

Gastrointestinal worms:

Haemonchus spp

Ostertagia spp (except inhibited Ostertagia larvae in cattle)

Nematodirus spp

Trichostrongylus spp

Cooperia spp

Oesophagostomum spp

Bunostomum spp

Downland Fluke and Worm Drench also removes most mature Fasciola spp (flukes) present in the bile duct of the liver.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Downland Fluke and Worm Drench should be administered as an oral drench. Dosing must be carried out accurately using a suitable gun system, at a rate of 7.5 mg levamisole hydrochloride and 15 mg oxcyclozanide per 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. Animals should be dosed according to their individual weight, and not dosed as per the heaviest animal in the group, otherwise signs of overdose may occur (see overdose information).

Thoroughly shake the container well before use to ensure that the two active substances are homogeneously resuspended and therefore the animals receive the correct dose.

Do not mix with other products.

DOSAGE GUIDE

Double strength: Follow dosage instructions carefully

Cattle: 2.5 ml per 10 kg bodyweight

Bodyweight Dose

50 kg (approx. 1 cwt) 12.5 ml

100 kg (approx. 2 cwt) 25 ml

150 kg (approx. 3 cwt) 37.5 ml

200 kg (approx. 4 cwt) 50 ml

250 kg (approx. 5 cwt) 62.5 ml

300 kg (approx. 6 cwt) 75 ml

Cattle over 300 kg should be given a further 2.5 ml per additional 10 kg bodyweight.

Sheep: 0.5 ml per 2 kg bodyweight

Bodyweight Dose

10 kg (approx. 22 lb) 2.5 ml

20 kg (approx. 44 lb) 5 ml

30 kg (approx. 66 lb) 7.5 ml

40 kg (approx. 88 lb) 10 ml

50 kg (approx. 110 lb) 12.5 ml

60 kg (approx. 132 lb) 15 ml

Sheep over 60 kg should be given a further 1 ml per additional 4 kg bodyweight.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Cattle (Meat & offal): 5 days

Sheep (Meat & offal): 5 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

Downland Fluke and Worm Drench 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.

Do not overdose. If recommended dosages are exceeded animals may exhibit signs of overdosage and toxicity. The effects of levamisole overdosage include impaired motor function i.e., muscle tremors, head shaking, increased salivation, facial swelling, oedema, scouring and in most severe cases, death.

At normal oxyclozanide dose levels, animals may show slight softening of the faeces with the occasional animal showing increased frequency of defecation and transient inappetence. Rarely, animals may also display signs of ataxia, incoordination, recumbency and depression. Photosensitisation associated with inflammation of the skin (particularly non pigmented skin e.g. muzzle, udder) has been observed to occur very rarely and which may be painful and lead to skin sloughing in severe cases. Additionally, rarely, sheep may show an allergic reaction such as submandibular oedema, ear flap oedema and swelling of the head. If such a reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

Oxyclozanide overdosage may produce inappetence and loss of bodyweight, dullness and some loosening of faeces in sheep, and possibly diarrhoea. These effects are occasionally enhanced in animals with severe liver damage and/or dehydration at the time of dosing.

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 Downland Fluke and Worm Drench. 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.

To date, no resistance to oxyclozanide has been reported. The use of this product should be based on local (regional, farm) epidemiological information about susceptibility of trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

User 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.

SHAKE THE CONTAINER WELL BEFORE USE.

10. EXPIRY DATE

D.O.M.:

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep the container in the 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.

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

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription.

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

Norbrook Laboratories Limited
Newry, Co. Down
BT35 6JP
Northern Ireland

Distributed By:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co Down
Northern Ireland
BT35 6QQ

On Behalf Of:

Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4169

17. MANUFACTURER'S BATCH NUMBER

B.N.:

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
{Container Label}

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A bright yellow, viscous suspension.

4. PACKAGE SIZE

Multidose low-density polyethylene containers of 1 litre, 2.5 litres and 4 litres.

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

Controls roundworm, lungworm and fluke 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 and 15 mg oxyclozanide per 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. Animals should be dosed according to their individual weight, and not dosed as per the heaviest animal in the group, otherwise signs of overdose may occur.

Thoroughly shake the container well before use to ensure that the two active substances are homogeneously resuspended and therefore the animals receive the correct dose

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Cattle (Meat & offal): 5 days

Sheep (Meat & offal): 5 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

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.

SHAKE THE CONTAINER WELL BEFORE USE.

For the user warnings and further information: See carton text.

10. EXPIRY DATE

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Exp:

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Do not store above 25°C. Protect from light.

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BT35 6QQ

On Behalf Of:

Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4169

17. MANUFACTURER'S BATCH NUMBER

B.N.:

A handwritten signature in black ink, appearing to read 'Dennett', is written over a horizontal line.

Approved: 04 May 2023