1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levafas Diamond Fluke and Worm Drench

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Levamisole hydrochloride	30 mg/ml
Oxyclozanide	60 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium metabisulphite (E223)	0.15 mg/ml
Tartrazine (E102)	0.11 mg/ml
Sodium methyl parahydroxybenzoate (E219)	1.8 mg/ml
Sodium citrate	
Anhydrous citric acid	
Disodium edetate	
Polysorbate 80	
Xanthan gum	
Antifoam M30	
Purified water	

A yellow viscous suspension

3. CLINICAL INFORMATION

3.1. Target species

Cattle, sheep.

3.2 Indications for use for each target species

For the treatment and control of both gastro-intestinal and pulmonary nematode infections and adult liver fluke infections in cattle and sheep. The veterinary medicinal product should be used in cases of parasitic gastroenteritis and lungworm caused by those organisms sensitive to treatment with Levamisole hydrochloride.

Levamisole is effective against mature and developing immature stages of a wide range of important nematode species and is highly effective against the following:

Lungworms:
Dictyocaulus spp.

Gastrointestinal worms:
Trichostrongyles spp.
Cooperia spp.
Ostertagia spp. (except inhibited *Ostertagia* larvae)
Haemonchus spp.
Nematodirus spp.
Bunostomum spp.
Oesophagostomum spp.
Chabertia spp.

The veterinary medicinal product also removes most mature *Fasciola* spp. (flukes) present in the bile ducts of the liver.

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4. Special warnings

Care should be taken when treating heavily pregnant animals or animals under stress from adverse weather conditions, poor nutrition, penning, handling etc. The veterinary medicinal product is not effective against Type II Ostertagiasis (winter scours) in cattle. 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.

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

3.5. Special precautions for use

Special precautions for safe use in the target species:

When using a dosing gun to administer this product, care must be taken to avoid dosing gun pharyngitis. After treatment, animals should be moved to clean pasture in order to prevent re-infection. Where this is not done, further dosing at 10-14 day intervals may be necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

When using, do not eat, drink or smoke.
Wash splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
Wash hands and exposed skin before meals and after work.
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 the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Species: Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea[1], Increased bowel movements (frequency)[1] Inappetence[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Photosensitisation[2] Skin inflammation[2] Skin slough[3]

[1] Transient.
[2] Particularly non pigmented skin e.g., muzzle, udder and which may be painful.
[3] In severe cases of photosensitisation.

Species: Sheep

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction[1] Swelling[1]

[1] Of the head.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent treatment with products containing organophosphorus compounds or diethylcarbamazine citrate should be avoided. These compounds should not be administered within a period of 14 days before or after treatment with the veterinary medicinal product.

3.9 Administration routes and dosage

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing. The veterinary medicinal product should be administered as an oral drench. Dosing may be carried out using a drenching bottle or a suitable gun system, at a rate of 7.5 mg levamisole hydrochloride/kg bodyweight and 15 mg oxyclozanide/kg bodyweight achieved by administering 25 ml per 100 kg bodyweight in cattle and 2.5 ml per 10 kg bodyweight in sheep.
The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

If recommended dosages are exceeded animals may exhibit signs of overdosage. The effects of levamisole overdosage include impaired motor function i.e. muscle tremors, head shaking and increased salivation. These effects are transient and more likely to be found in cattle than in sheep. The effects of oxyclozanide overdosage are dullness and some loosening of faeces in sheep and possible diarrhoea, inappetence and loss of weight in cattle. The effects are occasionally enhanced in animals with severe liver damage and/or dehydration at the time of dosing.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12. Withdrawal periods

Cattle:
Meat and offal: 28 days.

Sheep
Meat and offal: 10 days.

Animals must not be slaughtered for human consumption during treatment.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code: QP52AE51

4.2 Pharmacodynamics

Levamisole is an imidazothiazole that acts by interfering with parasite nerve transmission causing muscular paralysis. It is effective against adult and immature gastro-intestinal roundworm and lungworm infections. Oxyclozanide is a salicylanilide which is mainly active against adult liver flukes. It is distributed to the liver, kidney and intestines and is excreted in the bile.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3. Special precautions for storage

Do not store above 25ºC.
Protect from light.

5.4. Nature and composition of immediate packaging

Low density polyethylene containers of 1 litre, 2.5 litres, 4 litre, 10 litres and 10.5 litres (2 x 4 litres and 1 x 2.5 litres).

Not all pack sizes may be marketed.

5.5. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/024/001

8. DATE OF FIRST AUTHORISATION

01 October 1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12/04/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).