SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levafas Diamond Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
3.0% w/v Levamisole Hydrochloride
6.0% w/v Oxyclozanide

Excipients:
0.18%w/v sodium methylhydroxybenzoate (preservative)
0.05%w/v Disodium Edetate (antioxidant)
0.15%w/v Sodium Metabisulphite (antioxidant).
0.011%w/v Tartrazine E102 (colourant).

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension
A yellow viscous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep

4.2 Indications for use, specifying the target species

For the treatment and control of both gastrointestinal and pulmonary nematode infections, and adult liver fluke infections. Removes most mature *Fasciola* spp (flukes) present in the bile ducts of the liver

4.3 Contraindications

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

4.4 Special Warnings for each target species

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.

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing.

Do not exceed the recommended dosage.

4.5 Special precautions for use

i. Special precautions for use in animals

Care should be taken to estimate accurately the liveweight of animals to be treated. 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 section 4.10). It is important that the container is shaken thoroughly before use to ensure that the two active substances are homogeneously resuspended and therefore the animals receive the correct dose.

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

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.

4.6 Adverse reactions (frequency and seriousness)

At normal oxyclozanide dose levels, cattle 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.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

4.7 Use during pregnancy, lactation or lay

The product can be safely 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.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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.

Dosing must be carried out using a suitable gun system, at a rate of 7.5 mg/kg bodyweight levamisole hydrochloride and 15 mg/kg bodyweight oxyclozanide achieved by administering 2.5 ml per 10 kg bodyweight in cattle and 0.5 ml per 2 kg bodyweight in sheep.

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 section 4.10).

Do not mix with other products.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Cattle and sheep may be slaughtered for human consumption only after 5 days from the last treatment.

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

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QP52AE51

Pharmacotherapeutic group: Anthelmintics, Imidazothiazoles

5.1 Pharmacodynamic properties

Levamisole is an imidazothiazole that acts by interfering with parasite nerve transmission causing muscular paralysis. It is effective against adult and immature gastrointestinal 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Hydroxybenzoate
Disodium Edetate Dihydrate
Sodium Metabisulphite
Tartrazine (E102)
Trisodium Citrate
Citric Acid Anhydrous
Polysorbate 80
Xanthan Gum
Simeticone
Water Purified

6.2 Incompatibilities

None known

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

White low-density polyethylene flexipacks with screw fit white wadded polypropylene caps of 1 litre, 2.5 litres and 4 litres, containing a yellow viscous suspension.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

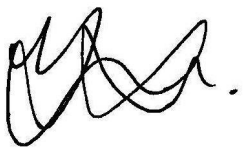
Vm 02000/4080

9. DATE OF FIRST AUTHORISATION

22 October 1986

10. DATE OF REVISION OF THE TEXT

April 2023



Approved: 17 April 2023