Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Levafas Diamond Fluke and Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Levamisole hydrochloride	3.0	% w/v
Oxyclozanide	6.0	% w/v

Excipients

Sodium metabisulphite (E223)	0.15	% w/v
Tartrazine (E102)	0.011	% w/v
Sodium methyl parahydroxybenzoate (E219)	0.18	% w/v

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 gastro-intestinal and pulmonary nematode infections and adult liver fluke infections in cattle and sheep. Levafas Diamond Fluke and Worm Drench 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.

Levafas Diamond Fluke & Worm Drench also removes most mature *Fasciola* spp. (flukes) present in the bile ducts of the liver.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substances.

4.4 Special warnings for each target species

Care should be taken when treating heavily pregnant animals or animals under stress from adverse weather conditions, poor nutrition, penning, handling, etc. Levafas Diamond Fluke and Worm Drench 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 Levafas Diamond Fluke and Worm Drench. 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.

4.5 Special precautions for use

Special precautions for use in animals
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.

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 inappetance. Rarely, sheep may show an anaphylactic reaction with swelling of the head.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

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 Levafas Diamond Fluke and Worm Drench.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, bodyweight 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.
Levafas Diamond Fluke and Worm Drench 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.

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

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.

4.11 Withdrawal period(s)

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.
Sheep may be slaughtered for human consumption only after 10 days from the last treatment.Do not use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, levamisole, combinations
ATCvet code: QP52AE51

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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate Anhydrous citric acid
Sodium metabisulphite (E223)
Disodium edetate
Polysorbate 80
Xanthan gum
Tartrazine (E102)
Sodium methyl parahydroxybenzoate (E219)
Antifoam M30
Purified water

6.2 Major 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 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene containers of 1 litre, 2.5 litres, 4 litres, 10 litres and 10.5 litres (2 x 4 litres and 1 x 2.5 litres).
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

January 2020