

IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10999/042/001**
Case No: 7006156

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, Newry, Co. Down BT35 6JP

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Levafas C Fluke and Worm Drench

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Levafas C Fluke and Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Levamisole (as Levamisole hydrochloride)	1.5	% w/v
Oxyclozanide	3.0	% w/v

Excipients

Sodium Methyl Parahydroxybenzoate (E219)	0.18	% w/v
Sodium Metabisulphite (E223)	0.15	% w/v
Tartrazine (E102)	0.011	% w/v

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 and 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. Cobalt which is involved in the metabolism of Vitamin B12 is present as a nutritional supplement.

Levafas C Fluke and Worm Drench should be used in cases of parasitic gastroenteritis and lungworm caused by those organisms sensitive to treatment with Levamisole hydrochloride.

Lungworms:

Dictyocaulus spp.

Gastrointestinal worms:

Trichostrongylus spp.

Cooperia spp.

Ostertagia spp. (except inhibited *Ostertagia* larvae)

Haemonchus spp.

Nematodirus spp.

Bunostomum spp.

Oesophagostomum spp.

Chabertia spp.

Levafas C Fluke and Worm Drench 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 C 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 C 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 inappetence.

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 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 Levafas C 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 C 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, 15 mg oxyclozanide/kg bodyweight and 0.4 mg Cobalt/kg bodyweight achieved by administering 50 ml per 100 kg bodyweight in cattle and 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 and sheep may be slaughtered for human consumption only after 6 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. Oxytoclozanide 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

Cobalt sulphate heptahydrate
Sodium methyl parahydroxybenzoate (E219)
Sodium metabisulphite (E223)
Disodium edetate
Tartrazine (E102)
Sodium citrate
Citric acid monohydrate
Polysorbate 80
Xanthan Gum
Antifoam M30
Purified water

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

Store below 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene containers of 1 litre, 2.5 litres, 5 litres and 10 litres with plastic screw top and plastic coated paper washers.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ltd.
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/042/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT