IRISH MEDICINES BOARD ACT 1995, as amended

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

VPA: **10915/004/001**
Case No: 7006886

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:

Ancare Ireland Ltd.

30 Coolmine Business Park, **Clonsilla Road**, **Dublin 15.**

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:

Levicare Hi-Mineral Oral Solution

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 **30/03/2009**.

Signed on behalf of the Irish Medicines Board

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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

Levicare Hi-Mineral Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Levamisole hydrochloride	3.75 % w/v
Excipients	
Methyl parahydroxybenzoate (E218)	0.1 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution.
A pink coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and cattle.

4.2 Indications for use, specifying the target species

For the control of mature and developing immature gastro-intestinal roundworm and lungworms in sheep. The product also contains cobalt and selenium as an aid in the prevention and treatment of deficiencies and to improve the performance of animals on cobalt and selenium deficient diets.

Warning: This product is not active against inhibited larvae of *Ostertagia* which may cause Type II winter scours.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.

Do not use at the same time as any other product containing cobalt or selenium without consulting a veterinarian. Do not exceed the stated dose volume and frequency. Do not use in areas with soils of high seleniferous content.

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 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

The product should be administered using a suitably calibrated drenching gun, taking care to avoid causing injury to the mouth and pharynx.

Due regard must always be given to physical condition, particularly of any animals in advanced pregnancy and / or stress from adverse weather conditions, poor nutrition, penning, handling etc.

This product should only be used in areas where deficiencies of cobalt and selenium are likely to occur.

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 skin and eyes 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 and fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Levamisole may be given to young, pregnant and lactating animals. Levamisole should not be administered to lactating animals producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer at the same time as any other selenium-containing product without consulting a veterinary surgeon.
Do not administer at the same time as a product containing nicotine-like compound(s).

4.9 Amounts to be administered and administration route

For oral administration only.

Shake well before use.

Using standard dosing equipment, administer orally.

Cattle: 3 ml per 15 kg bodyweight (7.5 mg levamisole, 1.45 mg Co, 0.08 mg Se per kg bodyweight).

Sheep: 3 ml per 15 kg bodyweight (7.5 mg levamisole, 1.45 mg Co, 0.08 mg Se per kg bodyweight)

Cattle

Bodyweight (kg)	Dose (ml)
45	9
90	18
135	27
180	36
225	45
270	54

Above 270 kg add 9 ml per 45 kg bodyweight.

Sheep

Bodyweight (kg)	Dose (ml)
UP to 15	3
16-20	4
21-25	5
26-30	6
31-35	7
36-40	8
41-45	9

Above 45 kg add 3 ml per 15 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. 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.

Use properly calibrated dosing equipment.

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

Symptoms are similar to those of poisoning by organophosphorus compounds: salivation, defecation, constriction of the pupils and respiratory distress.

4.11 Withdrawal Period(s)

Meat and offal: 21 days. Animals intended for human consumption may be slaughtered only after 21 days following the last treatment.

Not for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, imidazothiazoles
ATCvet code: QP52AE01

5.1 Pharmacodynamic properties

Levamisole is the laevo-enantiomer of tetramisole and is an anthelmintic imidazothiazole. It's anthelmintic action is characterised by paralysis of the worm through a neuromuscular inhibition of the depolarising type, leading to passive elimination of the worm.

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cobaltous sulphate 7H20 (Co)
Sodium selenate (Se)
Anhydrous citric acid
Methyl parahydroxybenzoate
Propylene glycol
Xanthan gum
Water

6.2 Incompatibilities

Do not administer additional trace elements cobalt and selenium.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Store below 25°C.
Protect from light and frost.
Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

Container:
White, food grade, high density polyethylene bottle.

Closure:
HDPE screw cap.

Pack size:
1, 2.5, 5 and 10 litres.

Not all pack sizes may be marketed.

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

Do not contaminate ponds, waterways of ditches with the product of used containers.

Dispose of used container safely.

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

Ancare Ireland Limited,
30 Coolmine Business Park
Clonsilla Road
Dublin 15

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10915/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th March 2009

10 DATE OF REVISION OF THE TEXT