IRISH MEDICINES BOARD ACT 1995, as amended

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

VPA: **10823/010/001**
Case No: 7006772

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:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **Ireland**

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:

Levapharm Injection 75 mg/ml

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

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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

Levapharm Injection 75 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:		
Active Substance		
Levamisole (as levasimole hydrochloride)	75	mg
Excipients		
Methyl Parahydroxybenzoate (E218)	1.5	mg
Sodium Metabisulphite	1.5	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear sterile solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

The product is a broad spectrum anthelmintic for use in the treatment and control of nematode infections. It should be used in cases of parasitic gastro-enteritis and lungworm disease caused by mature and developing immature forms of those organisms sensitive to treatment with Levamisole Hydrochloride including the following:

Lungworms (adult and larval stages):
Dictyocaulus spp.

Gastro-intestinal worms (adult and larval stages):
Trichostrongylus spp.
Cooperia spp.
Ostertagia spp. (except inhibited *Ostertagia* larvae in cattle)
Haemonchus spp.
Nematodirus spp.
Bunostomum spp.
Oesophagostomum spp.
Chabertia spp.

4.3 Contraindications

Do not use in animals known to be hypersensitive to Levamisole.

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

After treatment animals should be moved to clean pasture in order to prevent re-infection. Where this is not done further dosing at 21 day intervals may be necessary.

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

Wash splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
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)

Although normally non-irritant, the product may occasionally cause local reaction at the site of injection. This should resolve naturally in a short period of time.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant or lactating animals. However care should be taken to avoid unnecessary stress when handling heavily pregnant 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 Levamisole. Levamsiole is not affected by benzimidazole resistance.

4.9 Amounts to be administered and administration route

The product should be administered by subcutaneous injection at a rate of 7.5 mg levamisole hydrochloride/kg bodyweight (1 ml/10 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

The product is safe for use in cattle and sheep at the recommended dosages. However, if recommended doses are exceeded animals may exhibit signs of impaired motor functions such as muscle tremors and increased salivation, which are of a temporary nature.

4.11 Withdrawal Period(s)

Not to be used in cattle and sheep producing milk for human consumption. Cattle and sheep may be slaughtered for human consumption only after 14 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, imidazothiazoles
ATCvet code: QP52AE01

5.1 Pharmacodynamic properties

Levamisole Hydrochloride is the levo isomer of d1 2, 3, 5, 6 - Tetrahydro - 6 - phenyl - imidazo (2, 1-b) thiazole Hydrochloride. Levamisole was found to be active against adult and immature gastro-intestinal and pulmonary nematodes when administered to experimentally infected animals by the oral, subcutaneous, intramuscular or intraperitoneal routes. It is thought to act by paralysing the susceptible parasites which are then expelled from the alimentary canal.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Sodium Citrate
Citric Acid Anhydrous
Sodium Metabisulphite
Disodium Edetate
Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

Marketed in multidose collapsible polyethylene containers of 500 ml capacity which are sealed with nitryl closures and aluminium caps.

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

Chem-Pharm Ltd.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/10/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT