SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Downland Levamisole 7.5% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Levamisole Hydrochloride	7.5 %w/v

Excipients:

Methyl Hydroxybenzoate	0.150 %w/v
Sodium Metabisulphite	0.150 %w/v
Quinoline Yellow (E104)	0.10 %w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection.
A sterile, clear, yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep

4.2 Indications for use, specifying the target species

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.

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

In cases of lungworm infections, coughing may persist for a considerable time following successful treatment 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 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.

4.5 Special precautions for use

Special precautions for use in animals

Care should be taken to estimate accurately the liveweight of animals to be treated. After treatment animals should be moved to clean pasture in order to prevent re-infection.

Veterinary advice should be sought:

a) On appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing.

b) If the product does not achieve the desired clinical effect since other diseases, nutritional disturbances or anthelmintic resisitance might be involved.

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

Take care to avoid accidental self-injection

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)

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 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

Levamisole activity is not affected by benzimidazole resistance.

4.9 Amounts to be administered and administration route

Administer by subcutaneous injection at a rate of 7.5 mg Levamisole per kg bodyweight. Usual aseptic precautions should be observed. Cattle should be dosed at a rate of 1 ml of product per 10 kg bodyweight and sheep at a rate of 0.5 ml per 5 kg bodyweight.

Divide large doses between two or more injection sites. In order to minimise the risk of infection, needles should be changes frequently.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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

Cattle may be slaughtered for human consumption only after 28 days from the last treatment. Sheep may be slaughtered for human consumption only after 15 days from the last treatment.
This product must not be used in cattle and sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC Vet Code: QP52EA01

5.1 Pharmacodynamic properties

Levamisole Hydrochloride is the laevo isomer of dl 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 Hydroxybenzoate
Sodium Metabisulphate
Quinoline Yellow (E104)
Sodium Citrate Dihydrate
Citrate Acid Anhydrous
Disodium Edetate Dihydrate
Water for Injections

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 25ºC.
Protect from light.
In order to minimise the risk of infection, needles should be changed as frequently as possible.
Following withdrawal of the first dose, use the product within 28 days.

6.5 Nature and composition of immediate packaging

100ml, 250ml or 500ml low density clear polyethylene flexipacks with a nitryl rubber bung and an aluminium overseal.

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
Newry
Co. Down
BT35 6JP

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4333

9. DATE OF FIRST AUTHORISATION

24 April 1998

10. DATE OF REVISION OF THE TEXT

3rd September 2008