SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Low Volume 7.5% Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
7.5% w/v Levamisole Hydrochloride

Excipients:
0.15% w/v Methyl Hydroxybenzoate as antimicrobial preservative
0.011% w/v Tartrazine (E102) as dye
0.15% w/v Sodium Metabisulphite as an antioxidant
0.05% w/v Disodium Edetate Dihydrate as an antioxidant

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution
A clear yellow liquid

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. These include:

Haemonchus spp, *Ostertagia* spp (except inhibited Ostertagia larvae in cattle), *Nematodirus* spp, *Trichostrongylus* spp, *Cooperia* spp, *Oesophagostomum* spp, *Chabertia* spp, *Bunostomum* spp and *Dictyocaulus* spp.

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

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.

In cases of lungworm infection in cattle, coughing may persist for a considerable time following successful treatment with Levacide Low Volume. This is due to tissue damage caused by the parasites.

4.5 Special precautions for use

i. Special precautions for use in animals

For oral administration only
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 resistance might be involved.

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

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)

None

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 is not affected by benzimidazole resistance.

4.9 Amounts to be administered and administration route

Administer as an oral drench using a dosing gun system at a rate of 7.5 mg levamisole hydrochloride per kg bodyweight. 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.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Do not mix with other products

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

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, head shaking and increased salivation, which are of a temporary nature.

4.11 Withdrawal period

Cattle may be slaughtered for human consumption only after 14 days from the last treatment. Sheep may be slaughtered for human consumption only after 21 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: QP52AE01

5.1 Pharmacodynamic properties

Levamisole Hydrochloride is the levo 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 body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Hydroxybenzoate
Tartrazine (E102)
Sodium Metabisulphite
Disodium Edetate Dihydrate
Sodium Citrate Dihydrate
Citric Acid Anhydrous
Water Purified

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

Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

White, opaque low density polyethylene containers with screw fit polyethylene caps containing 1 and 2.5 litres. Also white, opaque low density polyethylene flexipacks with rubber nitryl bung and aluminium overseals containing 500ml.

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 02000/4081

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 03 February 1987

10. DATE OF REVISION OF THE TEXT

June 2010