Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide 1.5 %w/v SC Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Levamisole (as levamisole hydrochloride)	1.5 % w/v

Excipients

Methyl parahydroxybenzoate (E218)	0.15 % 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 solution.
A dark orange liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle
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. Cobalt, involved in the metabolism of Vitamin B12, and selenium whose function is closely related to that of Vitamin E, are present as nutritional supplements.

The following are susceptible parasite species:

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.

4.3 Contraindications

Do not use in animals known to be hypersensitive to Levamisole. This product should not be used in areas of high seleniferous soil content.

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.. The product 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 the product. 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

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

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)

None.

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 interactions

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.

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 or 5 ml of the product/10 kg bodyweight.
This dose rate will provide 0.4 mg Cobalt and 0.08 mg Selenium per 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. 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.

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)

Cattle and sheep may be slaughtered for human consumption only after 14 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 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 alimentary canal.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cobalt sulphate heptahydrate
Sodium selenate (anhydrous)
Methyl parahydroxybenzoate (E218)
Citric acid monohydrate
Disodium edetate
Sodium citrate
Sodium metabisulphite (E223)
Tartrazine (E102)
Purified water

6.2 Major 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

1 litre, 2.5 litres, 5 litres, and 10 litre multidose polyethylene container with plastic screw tops 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 derived from the use of such products

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 (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

January 2019