SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacide Pour-On Solution 20 %w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:	**w/v**
Levamisole	20.0 %
(as Levamisole Hydrochloride	26.2 %)

Excipients:

Patent blue (E131)	0.1 %

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution.
A dark blue solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Levamisole is a broad-spectrum anthelmintic indicated for use in cattle in the treatment and control of nematode infections such as parasitic gastro-enteritis and lungworm disease caused by the following mature and developing immature gastro-intestinal and pulmonary nematodes:

Lungworms - *Dictyocaulus viviparus*

Gastrointestinal worms - *Trichostrongylus* spp, *Cooperia* spp, *Ostertagia ostertagi* (except inhibited *O. ostertagi* larvae), *Haemonchus* spp, *Nematodirus* spp, *Bunostomum* spp, *Oesophagostomum* spp.

4.3 Contraindications

None

4.4 Special Warnings for each target species

In cases of lungworm infection coughing may persist for some time after treatment due to tissue damage.
For external use only.
Do not treat animals when wet, and where possible, for one hour post treatment, prevent treated animals from being exposed to rain.

4.5 Special precautions for use

i) Special precautions for use in animals

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.

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

Do not exceed the stated dose.

The bodyweight of animals should be assessed as accurately as possible before calculating the dose.

As with other anthelmintics, 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 effect, as other diseases,

nutritional disturbances or anthelmintic resistance may be present.

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

Highly flammable. Keep away from heat and sources of ignition.

Do not eat, drink or smoke when using this product. Wear rubber gloves, boots and waterproof bib-apron when applying this product. Avoid contact with skin and eyes. In case of accidental skin or eye contact, wash/irrigate splashes from skin and eyes immediately with clean water. If irritation persists seek medical advice. Remove any contaminated clothing immediately. Wash hands and exposed skin after handling this product and before meals. Use in a well ventilated area.

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)

The product is safe for use in cattle at the recommended dosage. In cases of overdosage (which only occurs at over five times the recommended dose rate), hyperaesthesia, tremor and occasionally diarrhoea may occur.

At the recommended dose rates animals should not show any adverse side effects. However, local skin irritation at the application site may be observed occasionally, characterised by subcutaneous oedema. Severe cases may show signs of epidermal flaking for which symptomatic treatment is recommended.

4.7 Use during pregnancy, lactation or lay

May be administered to pregnant or lactating animals but care should be taken when treating heavily pregnant animals or animals suffering stress from adverse weather conditions, poor nutrition, penning, handling etc.

4.8 Interaction with other medicinal products and other forms of interaction

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

4.9 Amounts to be administered and administration route

The pour-on is indicated for external transcutaneous administration to cattle.

The recommended dose rate is 10 mg levamisole/kg bodyweight equivalent to 2.5 ml per 50 kg bodyweight.

Bodyweight	**Dose**
Up to 50 kg (1 cwt)	2.5 ml
51-100 kg (1-2 cwt)	5 ml
101-150 kg (2-3 cwt)	7.5 ml
151-200 kg (3-4 cwt)	10 ml
201-250 kg (4-5 cwt)	12.5 ml
251-300 kg (5-6 cwt)	15 ml
301-350 kg (6-7 cwt)	17.5 ml

Above 350 kg give a further 2.5 ml for each additional 50 kg bodyweight.

Dose all young cattle in early summer and if possible move to clean pasture. Cattle should be dosed on first signs of lungworm infection.

For external administration only. Pour on from the calibrated dispenser or using a standard dosing gun. Apply along the flattest part of the backline at the rate of 10 mg levamisole/kg bodyweight, equivalent to 2.5 ml per 50 kg bodyweight.

For 500 ml twin neck dispenser, simply squeeze the bottle to allow the appropriate amount of liquid into the calibrated dispenser. Apply along the backline and let it "pool" on the flattest part of the animal's back. The 2.5 L “Jerry-can” should be used in conjunction with a standard dosing gun.

The 2.5 litre “Jerry-can” should be used in conjunction with a standard dosing gun. Use of other equipment is not recommended as the product may have a detrimental effect on certain components.

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

In cases of overdosage (which only occurs at over five times the recommended dose rate), hyperaesthesia, tremor and occasionally diarrhoea may occur.

4.11 Withdrawal period

Animals must not be slaughtered for human consumption during treatment.

Cattle (meat): 28 days.

Do not use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATC Vet Code: QP52AE01

5.1 Pharmacodynamic properties

Levamisole is the *laevo* isomer of tetramisole, a racemic imidazothiazole derivative, and is a member of the imidazothiazole group of anthelmintics.

Levamisole is a broad spectrum anthelmintic which displays excellent activity against mature and developing immature stages of gastro-intestinal and pulmonary nematodes.

By behaving as a cholinergic agonist of the nematode nervous system levamisole mimics the action of the excitatory neurotransmitter, acetylcholine, which results in sustained (spastic) muscle paralysis. By inhibiting fumarate reductase, levamisole also has a minor role to play in disrupting the nematodes energy pathway. However this is of limited consequence in comparison to its role as a paralysing agent.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue (E131)
Isopropyl Myristate
Denatonium Benzoate
Isopropyl Alcohol

6.2 Incompatibilities

Cattle must not be treated within a period of 14 days before or after treatment with organophosphorous compounds.

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: 6 months.

6.4 Special precautions for storage

Do not store above 25ºC. Do not freeze.
Protect from light.
Store tightly closed in original container.
Following withdrawal of the first dose, use the product within 6 months.

6.5 Nature and composition of immediate packaging

500 ml translucent, colourless, high-density polyethylene, twin neck squeeze and pour packs, with plastic screw caps and low-density polyethylene faced aluminium foil heat seals.

2.5 litre white opaque high-density polyethylene jerry-can, with plastic screw caps with low-density polyethylene faced aluminium foil heat seals.

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.
Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4138

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 1997

10. DATE OF REVISION OF THE TEXT

December 2008