Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vermisole 75 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Levamisole Hydrochloride	75	mg

Excipients		
Sodium metabisulphite	1	mg
Parahydroxybenzoates	1	mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

For the treatment and control of lungworms, stomach and bowel worm infestation (except inhibited Ostertagia) in cattle and sheep, caused by the following organisms.

Lungworms: *Dictyocaulus* spp.
Stomach and Bowel Worms: *Bunostomum* spp., *Chabertia* spp., *Cooperia* spp., *Haemonchus* spp., *Nematodirus* spp., *Oesophagostomum* spp., *Ostertagia* spp. (except inhibited Ostertagia larvae in cattle), *Strongyloides* spp., *Trichostrongylus* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

The product is not suitable for the treatment of Type II Ostertagiasis (Winter Scours) in cattle.
The product can be given to pregnant and lactating animals, unweaned lambs and debilitated stock (in the absence of inter-current disease); also at the same time as treatment for other conditions or when vaccinating.

Due regard must always, of course, be given to the physical condition of animals undergoing treatment, particularly those in advanced pregnancy and/or stress from adverse weather conditions, poor nutrition, penning, handling, etc.

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

Not applicable.

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.
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)

Coughing may persist for several weeks after injection due to tissue damage caused by lungworm. A bout of coughing may occur for up to 30 minutes following injection due to expulsion of adult worms from the bronchi.

A slight non-persistent reaction may occur at the injection site, mainly in cattle, but this is very rarely of any consequence. In order to minimise risk of infection, needles should be changed as frequently as possible.

4.7 Use during pregnancy, lactation or lay

The product may be given to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

Animals should not be treated simultaneously with products containing organophosphorous compounds or diethylcarbamazine citrate. Any such treatment should not take place within a period of 14 days before or after use of the product.

4.9 Amounts to be administered and administration route

By subcutaneous injection.
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.

Cattle: 5 ml per 50 kg liveweight (approx 1 cwt)
7.5 mg levamisole hydrochloride per kg bodyweight.

Liveweight

Up to 75 kg (approx. 1 ½ cwt) 5 ml
76 - 125 kg (1 ½ - 2 ½ cwt) 10 ml
126 - 175 kg (2 ½ - 3 ½ cwt) 15 ml
176 - 225 kg (3 ½ - 4 ½ cwt) 20 ml
226 - 300 kg (4 ½ - 6 cwt) 25 ml
Over 300 kg (over 6 cwt) 5 ml per 50 kg

Sheep: 1 ml per 10 kg liveweight
7.5 mg levamisole hydrochloride per kg bodyweight.

Liveweight:

Up to 13 kg (28 lbs) 1.0 ml
13 - 17 kg (28 - 37 lbs) 1.5 ml
18 - 23 kg (38 - 51 lbs) 2.0 ml
24 - 34 kg (52 - 75 lbs) 3.0 ml
35 - 45 kg (76 - 99 lbs) 4.0 ml
46 - 55 kg (100 - 121 lbs) 5.0 ml
over 55 kg (over 121 lbs) 1.0 ml per 10 kg

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

At normal dose levels, animals rarely show any side-effects. At twice the therapeutic dose, calves may show some increased alertness and salivation. The effects of overdosage are transient and include head shaking, salivation and slight muscle tremors. They are more likely to be observed in cattle than in sheep.

4.11 Withdrawal period(s)

Animals intended for human consumption must not be slaughtered during treatment.

Cattle intended for human consumption may only be slaughtered from 7 days after the last treatment.

Sheep intended for human consumption may only be slaughtered from 14 days after the last treatment.

Not to be used in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, levamisole
ATCvet code: QP52AE01

5.1 Pharmacodynamic properties

The product is a multidose injection containing 7.5 g Levamisole Hydrochloride in each 100 ml.

Levamisole Hydrochloride is a member of the imidazothiazole group of anthelmintics. The drug acts as a ganglion stimulant in sensitive parasite nematodes by exerting a cholinomimetic effect. This results in sustained muscle contraction and paralysis of the parasite.

5.2 Pharmacokinetic particulars

Subcutaneous injection of the product in cattle and sheep results in therapeutic concentrations of levamisole in the blood. Following absorption, levamisole is extensively metabolised in the liver.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Disodium Edetate
Parahydroxybenzoates
Sodium Citrate
Anhydrous Citric Acid
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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°C.

6.5 Nature and composition of immediate packaging

A clear, colourless, aqueous solution in a 500 ml low density polyethylene flexipack with a chloro/bromobutyl rubber wad and an aluminium tamper-evident over-seal.

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

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/045/001

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

June 2019