Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vermisole Worm Drench for Cattle and Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Levamisole Hydrochloride	1.50%	w/v

Excipients

Methyl parahydroxybenzoate	0.15%	w/v
Tartrazine (E102)	0.10%	w/v

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 and sheep.

4.2 Indications for use, specifying the target species

For the treatment and control of lungworm and stomach and bowel worm infestation in cattle and sheep, caused by the following organisms:

Dictyocaulus spp.
Trichostrongylus spp.
Cooperia spp.
Ostertagia spp. (except inhibited Ostertagia larvae in cattle)
Haemonchus spp.
Nematodirus spp.
Bunostomum spp.
Oesophagostomum spp.
Chabertia spp.
Strongyloides 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 can be given to pregnant and lactating animals, unweaned lambs and debilitated stock (in the absence of intercurrent disease); also at the same time as treatment for other conditions or when vaccinating.

Levamisole is not suitable for the treatment of Type II Ostertagiasis (Winter Scours) in cattle.

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

When using a drenching gun to administer the product, take care not to injure the throat with the nozzle of the gun.
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.

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 some sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Following the treatment of lungworm infection in cattle with the product, clinical signs may cease within 48 hours, but where lung damage is extensive, coughing can persist for several weeks. Both cattle and sheep sometimes cough for 15-30 minutes after treatment whilst adult worms are expelled from the bronchi.

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 Organophosphorus 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

For oral administration.
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 10 kg bodyweight (7.5 mg Levamisole hydrochloride per kg bodyweight).

Liveweight
Up to 75 kg (approx. 1 ½ cwt) 25 ml
76 - 125 kg (1 ½ - 2 ½ cwt) 50 ml
126 - 175 kg (2 ½ - 3 ½ cwt) 75 ml
176 - 225 kg (3 ½ - 4 ½ cwt) 100 ml
226 - 300 kg (4 ½ - 6 cwt) 125 ml
Over 300 kg (over 6 cwt) 50 ml per 100 kg

Sheep: 1 ml per 2 kg bodyweight (7.5 mg levamisole hydrochloride per kg bodyweight)

Liveweight
Up to 13 kg (28 lbs) 5.0 ml
13 - 17 kg (28 - 37 lbs) 7.5 ml
18 - 23 kg (38 - 51 lbs) 10.0 ml
24 - 34 kg (52 - 75 lbs) 15.0 ml
35 - 45 kg (76 - 99 lbs) 20.0 ml
46 - 55 kg (100 - 121 lbs) 25.0 ml
over 55 kg (over 121 lbs) 5.0 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 levamisole 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 14 days after the last treatment.

Sheep intended for human consumption may only be slaughtered from 21 days after the last treatment.

Not for use 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 drench containing 1.5 g Levamisole Hydrochloride in each 100 ml.

Levamisole hydrochloride is a member of the imidothiazole 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

Following oral administration of levamisole to cattle or sheep the drug is rapidly absorbed, peak concentrations in plasma being reached within 30 minutes of dosing.

Following absorption, levamisole is extensively metabolised in the liver.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Disodium Edetate
Methyl Parahydroxybenzoate
Sodium Citrate
Citric Acid Anhydrous
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

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

High density polyethylene containers sealed with a tamper-evident polyethylene cap containing 5 litres of a clear, yellow coloured aqueous solution.

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
Tallaght
Dublin 24
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/046/001

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