

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10990/017/001

Case No: 7002259

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Univet Limited

Tullyvin, Cootehill, Co. Cavan., Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Ascara Worm Drench 1.5%w/v

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ascara Worm Drench 1.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Levamisole Hydrochloride 15.0 mg

Excipients

Methyl Parahydroxybenzoate 1.0 mg

Sodium Metabisulphite 0.5 mg

Quinoline Yellow (E104) 0.132 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

ASCARA WORM DRENCH 1.5% w/v is a broad spectrum anthelmintic for the treatment of Nematode Infections in Cattle. Ascara Worm Drench 1.5% w/v should be used in cases of parasitic gastro-enteritis and lungworm caused by the following:

- Lungworms:

Dictyocaulus spp.
- Trichostrongylides:

Trichostrongylus spp.

Cooperia spp.

Ostertagia spp. (except inhibited larvae causing Type II Winter Scour)

Haemonchus spp.

Nematodirus spp.
- Strongyles:

Bunostomum spp.

Oesophagostomum spp.

Chabertia spp.

4.3 Contraindications

Concurrent treatment with organophosphates and/or diethylcarbamazine is contraindicated within a period of 14 days before/after Levamisole treatment.

Do not use in animals with a known hypersensitivity to Levamisole.

4.4 Special warnings for each target species

Carefully estimate the live weight of animals.

Use only properly calibrated dosing equipment.

4.5 Special precautions for use

Special precautions for use in animals

Avoid overdosing.

Where a dosing gun is used to administer the product, care must be taken to avoid injury to the animal i.e. dosing gun pharyngitis.

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

Wash splashes from eyes and hands immediately.

Wash hands after use

4.6 Adverse reactions (frequency and seriousness)

Accidental overdosage - animals may become hyperactive and excitable, with head shaking, salivation and muscle twitching. These effects are transient.

4.7 Use during pregnancy, lactation or lay

This product is safe for use during pregnancy.

Do not use in cattle producing milk for human consumption or for milk products for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent treatment with organophosphates and/or diethylcarbamazine is contraindicated.

4.9 Amounts to be administered and administration route

Ascara Worm Drench 1.5% w/v should be administered as an oral drench at a rate of 7.5 mg levamisole/kg bodyweight or 5 ml *Ascara Worm Drench 1.5% w/v* per 10 kg bodyweight.

Cattle Bodyweight kg Dose ml

50 kg	25 ml
100 kg	50 ml
150 kg	75 ml
200 kg	100 ml
250 kg	125 ml
300 kg	150 ml

To be given as an oral drench.

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

Accidental overdosage - animals may become hyperactive and excitable, with head shaking, salivation and muscle twitching. These effects are transient.

On the basis of the available information, it is clear that while levamisole does not have the safety index of some of the alternative anthelmintics (e.g. the benzimidazoles), its safety is adequate given careful usage and reasonably accurate weight estimation in domestic ruminants. This point is raised on the label and package insert. Its field usage over the years since its first introduction supports this conclusion. Furthermore, where toxic signs have occurred at dose levels two to three times over the recommended level, the signs have been transient with the vast majority of animals showing signs recovering in a few hours at most.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Animals intended for human consumption may only be slaughtered from 28 days after the last treatment.

Do not use in cattle producing milk for human consumption or for milk products for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product *Ascara Worm Drench 1.5% w/v* is an oral drench product containing the anthelmintic, levamisole HCl.

Levamisole HCl

Levamisole, the active ingredient of the product, is given as (-)-2,3,5,6-tetrahydro-6-phenylimidazo[2,1-b]thiazole by Roberson (1988). The details of its discovery are given by Janssen (1976) and Symeons, de Cree, Van Bever and Janssen (1978).

ASCARA WORM DRENCH is an oral drench product for the treatment of the common nematode parasites of cattle (including lung worm - *Dictyocaulus* spp.) in Ireland.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Citric Acid Monohydrate.
Sodium Citrate
Disodium Edetate
Quinoline Yellow (E104)
Sodium Metabisulphite
Purified Water

6.2 Incompatibilities

Concurrent treatment with organophosphates and/or diethylcarbamazine is contraindicated within a period of 14 days before/after levamisole treatment.

6.3 Shelf-life

The shelf life is two years from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A clear yellow solution in 2.5 and 5 L HDPE clear rigid, screw cap, containers.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product and waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd.,
Tullyvin,
Co. Cavan,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004