

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10863/001/001**
Case No: 7003067

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Sheelan Veterinary Practice

Oldcastle Road, Ballyjamesduff, Co. Cavan, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Sheelantic Worm Drench

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sheelantic Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance

Levamisole hydrochloride 15.0 mg
(equivalent to 12.7mg Levamisole)

Excipients

Methyl parahydroxybenzoate 1.0 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

A broad spectrum anthelmintic for the treatment of Nematode infections. Sheelantic Worm Drench should be used in cases of parasitic gastroenteritis and lungworm caused by the following:

Lungworms:

Dictyocaulus sp.

Trichostrongylides:

Trichostrongylus sp.

Cooperia sp.

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

Haemonchus sp.

Nematodirus sp.

Strongyles:

Bunostomum sp.

Oesophagostomum sp.

Chabertia sp.

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

Use only properly calibrated dosing equipment.
Carefully estimate the liveweight of animals before use.
Avoid overdosing.

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)

None when administered in accordance with label recommendations.

4.7 Use during pregnancy, lactation or lay

This product may be used in pregnant and lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

Animals should not receive concurrent treatment with organophosphates and/or diethylcarbamazine within a period of 14 days before/after levamisole treatment.

4.9 Amounts to be administered and administration route

For administration as an oral drench at a rate of 7.5 mg levamisole/kg bodyweight or 5ml Sheelantic Worm Drench 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

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

Accidental overdosage - animals may become hyperactive and excitable, with head shaking, salivation and muscle twitching. Where toxic signs occur at dose levels two to three times over the recommended level, the signs are typically transient with the vast majority of animals showing signs recovering in a few hours at most.

4.11 Withdrawal Period(s)

Cattle intended for human consumption may only be slaughtered from 28 days after the last treatment. Do not use in cows producing milk for human consumption or for milk products for human consumption

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product *Sheelantic* is an oral drench product containing the anthelmintic, levamisole HCl ((-)-2,3,5,6-tetrahydro-6-phenylimidazo [2,1-b]thiazole).

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

Shelf-life of the veterinary medicinal product as packaged for sale: 3 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

HDPE 1,2.5 and 5L clear, screw cap containers.

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

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

7 MARKETING AUTHORISATION HOLDER

Sheelin Veterinary Practice
Oldcastle Road
Ballyjamesduff
Co. Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10863/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd January 2003

10 DATE OF REVISION OF THE TEXT

21st December 2006