IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10545/002/001**
Case No: 7002446

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Janssen Cilag Ltd.

Saunderton, **High Wycombe**, **Buckinghamshire HP14 4HJ**, **United Kingdom**

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:

Ovitelmin Drench 5% w/v Oral Suspension

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

Ovitelmin Drench 5% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:	**Quantity:**
Mebendazole	5% w/v.
Excipients:	
Methyl Parahydroxybenzoate.	0.18% w/v (antimicrobial)
Propyl Parahydroxybenzoate	0.02% w/v (antimicrobial)
Sodium Benzoate	0.0075% w/v (antioxidant)

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

For the treatment and control of roundworm, lungworm and tapeworm infestations caused by:

Roundworms:
Haemonchus contortus
Cooperia spp.
Strongyloides papillosus
Oesophagostomum spp.
Chabertia ovina
Bunostomum spp.
Trichostrongylus spp.
Trichuris ovis
Ostertagia spp.
Nematodirus spp.

Lungworms:
Dictyocaulus filaria

Tapeworms:
Moniezia expansa
Avitellina centripunctata

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

As with all anthelmintics caution must be exercised when using drenching guns to avoid damage to the pharyngeal area.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

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

Wash splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

Not observed at recommended dosage.

4.7 Use during pregnancy, lactation or lay

May be given to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.9 Amounts to be administered and administration route

Oral administration.
The recommended dosage is 15mg/kg bodyweight (1 ml of Ovitelmin contains 50mg mebendazole). Ovitelmin drench is readily administered through standard dosing equipment.

The following dosing schedules are proposed for ewes:

1. Dose shortly before lambing to reduce pasture contamination.

2. Dose 4-6 weeks after lambing to control “spring rise” and subsequent pasture contamination.

3. Dose once during late autumn to control over-wintering larvae of lungworm, *Osteragia* and *Nematodirus*.

The following dosing schedules are proposed for lambs:

1. Dose lambs at 1 month for maximum economy and growth.

2. Dose at 4-6 week intervals as necessary to control re-infection.

For *Nematodirus* infestation - dose at fortnightly intervals throughout the period of risk - usually May-June.
Sheep should be moved to “clean” pasture after dosing.

Dose Rate and Recommendations:

Liveweight	Dose		Ex 1 litre	Ex 2.5 litre	Ex 5 litre
Lambs:					
under 16 kg	5	ml	200	500	1000
16-23 kg	7.5	ml	133	332	665
24-32 kg	10	ml	100	250	500
33-41 kg	12.5	ml	80	200	400
Sheep:					
41-46 kg	15	ml	67	167	335
47-57 kg	17.5	ml	57	142	285
58-64 kg	20	ml	50	125	250

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

Not applicable.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered until 14 days after the last treatment.
This product must not be used in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ovitelmin is a synthetic anthelmintic which is highly active against lungworms, gastrointestinal nematodes and cestodes in sheep.

Mode of action:
Mebendazole has a selective action on gastrointestinal parasites in the host. This is based on an interaction with the microtubular system in the absorbing cells, which produces an irreversible lytic destruction of these cells and results in death of the worm.

5.2 Pharmacokinetic properties

Mebendazole is not very soluble and is only slightly absorbed from the gastrointestinal tract. Consequently, mebendazole is eliminated almost unaltered via faeces after oral administration of therapeutic doses to sheep. The slight fraction that is absorbed produces maximum plasma levels within 24 hours of administration. The absorbed fraction is metabolised by the liver. The metabolites are mainly eliminated via urine. Seven days after treatment, tissue examination reveals negligible quantities of mebendazole.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Microcrystalline Cellulose and Carboxymethylcellulose Sodium
Methylcellulose (15 mPa.s)
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Docusate sodium
Sodium Benzoate
Citric Acid Monohydrate
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
60 months.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Polyethylene bottles of 1, 2.5 and 5 Litres, containing white to cream coloured suspension.
Closure: Screw cap (white urea) with aluminium/glue/high density polyethylene induction seal.

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

Do not contaminate ponds, waterways or ditches with product or used containers.
Dispose of used containers safely.

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

Janssen-Cilag Limited,
Saunderton,
High Wycombe,
Buckinghamshire, HP14 4HJ,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10545/2/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004.

10 DATE OF REVISION OF THE TEXT

1st June 2007