IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10019/022/001**
Case No: 7006363

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Pfizer Healthcare Ireland

Trading as Pfizer Animal Health, **Ringaskiddy**, **Co. Cork**, **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:

Valbazen 2.5% Total Spectrum Wormer, 2.5 %w/v

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.

The authorisation,unless revoked, shall continue in force from **14/07/2009** until .

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

VALBAZEN 2.5% Total Spectrum Wormer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Albendazole	2.50	% w/v
Excipients		
Potassium sorbate	0.15	% w/v
Benzoic acid	0.18	% w/v
Tartrazine (E 102)	0.0005	% w/v
Acid Brilliant Green BS (E142)	0.00022	% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep

4.2 Indications for use, specifying the target species

For the control of benzimidazole susceptible mature and developing immature forms of the following internal parasites of cattle and sheep.

Cattle: Gastro-intestinal roundworms: *Ostertagia, Cooperia, Trichostrongylus, Haemonchus, Bunostomum, Oesophagostomum and Strongyloides* spp.
Lungworms: *Dictyocaulus viviparus*

Sheep: Gastro-intestinal roundworms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus* (including *N.battus*), *Chabertia* and *Oesophagostomum* spp.
Lungworms: *Dictyocaulus filaria*

For the control of tapeworms, *Moniezia* spp., in cattle and sheep.

For the control of adult liver fluke, *Fasciola hepatica,* in cattle and sheep.

In cattle it is usually effective against inhibited larvae of *Cooperia* and *Ostertagia.*

In sheep it is usually effective against inhibited larvae of benzimidazole susceptible *Ostertagia.*

The product is ovicidal.

4.3 Contraindications

Do not dose ewes at the 'fluke and worm' dose rate (7.5 mg/kg) during tupping and for 1 month after removing rams.
Do not administer to 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

Intensive use or mis-use of anthelminthics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

Care must be taken to avoid injury to the pharyngeal region when dosing lambs and sheep. Valbazen is not recommended for the treatment of acute fascioliasis in sheep.

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Direct contact with the skin should be kept to a minimum.
Wear suitable protective clothing including impermeable rubber gloves.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Side effects are not to be expected following treatment.

4.7 Use during pregnancy, lactation or lay

In sheep, do not use at the fluke and worm dose rate during the first month of pregnancy.
Use of the product as recommended is not expected to interfere with reproductive performance of bulls, rams or pregnant cattle.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Shake container before use.

The product is given as an oral drench and is suitable for use with most types of automatic drenching equipment.

CATTLE
Worm dose
Approximately 7.5 mg albendazole per kg bodyweight.
(7.5ml per 25 kg bodyweight)
(10 ml per 25 kg bodyweight)

Fluke and worm dose
Approximately 10 mg albendazole per kg bodyweight.

Bodyweight (kg)	Worm Dose (ml)	Fluke & Worm Dose (ml)
Up to 50	15	20
51 – 100	30	40
101 – 150	45	60
151 – 200	60	80
201 – 250	75	100
251 – 300	90	120
301 – 350	105	140
over 350	A further 15 ml for each 50 kg	A further 20 ml for each 50 kg

SHEEP
Worm dose
Approximately 5 mg albendazole per kg bodyweight
(2 ml per 10 kg bodyweight)

Fluke and worm dose
Approximately 7.5 mg albendazole per kg bodyweight
(3 ml per 10 kg bodyweight)

Bodyweight (kg)	Worm Dose (ml)	Fluke & Worm Dose (ml)
Up to 10	2	3
11 – 20	4	6
21 – 30	6	9
31 – 40	8	12
41 – 50	10	15
51 – 60	12	18
61 – 70	14	21
Over 70	A further 2 ml for each 10 kg	A further 3 ml for each 10 kg

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

Moderate overdosage is unlikely to cause adverse reactions in healthy animals, but note Sections 4.3 and 4.7.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 14 days from the last treatment.
Sheep may be slaughtered for human consumption only after 10 days from the last treatment.

Milk for human consumption must not be taken during treatment.
Milk for human consumption may be taken from cows only after 72 hours from the last treatment.
Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Although not all aspects of the mode of action of benzimidazoles are known, there is evidence to suggest that three mechanisms are involved:

- inhibition of microtubule polymerisation
- inhibition of intestinal glucose resorption
- inhibition of fumarate reductase

5.2 Pharmacokinetic properties

The pharmacokinetics of albendazole have been extensively studied in both the target species (cattle and sheep) as well as in laboratory animals (mice and rats) and in humans for comparative purposes.

A number of general characteristic pharmacokinetic features have arisen from these studies:

- elimination from the tissues is rapid, no retention in deep compartments of the body has been described.
- there is an enterohepatic cycle, but its effect on the rate of elimination from tissues seems to be quantitatively minor following oral administration. Benzimidazoles are always extensively metabolised by mammals.
- metabolites from oxidation and hydrolysis, which are more soluble than the parent molecule, prevail in blood, tissues, bile and urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate
Benzoic acid
Tartrazine (E 102)
Acid Brilliant Green BS (E142)

6.2 Incompatibilities

None known.

6.3 Shelf-life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 and 2.5 litre translucent white high density polyethylene container with a polypropylene screw cap containing a pale green aqueous suspension.

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

Pfizer Sales Ireland,
Trading as Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/22/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004