IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10545/031/001**
Case No: 7004500

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:

Janssen Cilag Ltd.

50-100 Holmers Farm Way, **High Wycombe**, **Buckinghamshire HP12 4EG**, **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:

Oxfendex 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.

The authorisation,unless revoked, shall continue in force from **09/07/2008** until **27/10/2010**.

Signed on behalf of the Irish Medicines Board

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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

Oxfendex Oral Suspension 2.265% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Oxfendazole	2.265	% w/v
Excipients		
Formaldehyde	0.20	% w/v
Citric acid anhydrous	0.40	% w/v
Potassium sorbate	0.18	% 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-sensitive mature and immature gastrointestinal roundworms, lungworms and tapeworms in cattle and sheep, including:

Gastro-intestinal roundworms:
Ostertagia spp.
Haemonchus spp.
Trichostrongylus spp.
Nematodirus spp, including *N. battus*
Cooperia spp.
Capillaria spp.
Oesophagostomum spp.
Chabertia spp.
Trichuris spp.
Lungworms
Dictyocaulus spp.
Tapeworms:
Monezia spp.

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

Special precautions for use in animals

Do not exceed stated dose. When treating sheep, great care must be taken to avoid trauma to the pharyngeal area with nozzle of drenching guns.

Assess bodyweight as accurately as possible before calculating dosage.
Intensive use or misuse of the anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with your veterinary surgeon.

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)

None known.

4.7 Use during pregnancy, lactation or lay

Oxfendazole is not embryotoxic. This product can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Shake well before use. Using standard drenching equipment administer orally. The recommended dose rates are:

Cattle, 4.5 mg Oxfendazole/kg
Sheep, 5.0 mg Oxfendazole/kg

CATTLE		SHEEP	
Liveweight	*Dose*	*Liveweight*	*Dose*
100 kg (2 cwt)	20 ml	Up to 15 kg	3 ml
150 kg (3 cwt)	30 ml	16 – 20 kg	4 ml
200 kg (4 cwt)	40 ml	21 – 25 kg	5 ml
250 kg (5 cwt)	50 ml	26 – 30 kg	6 ml
300 kg (6 cwt)	60 ml	31 – 35 kg	7 ml
350 kg (7 cwt)	70 ml	36 – 40 kg	8 ml
400 kg (8 cwt)	80 ml	41 – 45 kg	9 ml
Over 400 kg	Give 10 ml/50 kg	Over 45 kg	Give 1 ml/5 kg

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

The product is very well tolerated at the recommended dose rates. In the case of accidental overdosage, depression and anorexia may occur.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment.
Cattle and sheep intended for human consumption may only be slaughtered from 28 days after the last treatment. Milk intended for human consumption may only be taken from cows after 4 days from the last treatment.

Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Oxfendazole is an anthelmintic belonging to the benzimidazole (I – BZ) class of compounds.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Citric Acid
Formaldehyde Solution
Propylene Glycol
Polyethylene Glycol 6000
Polyoxyl 40 Stearate
Potassium Sorbate
Colloidal Anhydrous Silica
Xanthan Gum
Water Purified

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life: two years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Container: White food grade, high density polyethylene pack.
Closure: HDPE screw cap.
Pack size: 1, 2.5, 5 and 10 litres.
Contents: Aqueous off-white free flowing 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

Janssen - Cilag Ltd.
50 - 100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/31/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th October 2005

10 DATE OF REVISION OF THE TEXT

9th July 2008