IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/059/001**
Case No: 7005215

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:

Norbrook Laboratories Limited

Station Works, **Newry**, **Co. Down BT35 6JP**

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:

Parafend 2.265% 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 previously revoked, shall continue in force from **09/02/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Parafend 2.265 % Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Oxfendazole	2.265 % w/v
Excipient	
Sodium Methyl Parahydroxybenzoate	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

Parafend 2.265% is a broad spectrum anthelmintic for the treatment and control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in cattle and sheep. Parafend 2.265% is ovicidal for strongyle eggs.

For the treatment of cattle and sheep infested with benzimidazole susceptible strains of the following species:

GASTRO-INTESTINAL ROUNDWORMS:

Ostertagia spp., *Haemonchus* spp., *Nematodirus* spp., including N. *battus*, *Trichostrongylus* spp., *Cooperia* spp., *Bunostomum* spp., *Oesophagostomum* spp., *Chabertia* spp., *Capillaria* spp., *Trichuris* spp..

LUNGWORMS: *Dictyocaulus* spp.
TAPEWORMS: *Moniezia* spp.

In cattle it is also effective against inhibited larvae of *Cooperia* spp. and usually effective against inhibited/arrested larvae of *Ostertagia* spp.. In sheep it is effective against inhibited/arrested larvae of *Nematodirus* spp., and benzimidazole susceptible *Haemonchus* spp. and *Ostertagia* spp..

4.3 Contraindications

Parafend 2.265% is contra-indicated 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

As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional disturbances or anthelmintic resistance may be involved.

4.5 Special precautions for use

i) Special precautions for use in animals
As with any husbandry procedure, care should be taken when handling the animals especially when inserting the dosing gun nozzle into the animal's mouth. Unnecessary force should not be used as this may cause damage to the mouth and pharyngeal region.
Equipment should be thoroughly cleaned before and after dosing.
Do not exceed the stated dose.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with the skin and eyes. Wash any splashes immediately with cold water.

iii) Other precautions
None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Parafend is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.
Shake well before use.
Cattle: 4.5 mg oxfendazole per kg bodyweight.

Bodyweight	Dose
100kg (2 cwt)	20ml
150kg (3 cwt)	30ml
200kg (4 cwt)	40ml
250kg (5cwt)	50ml
300kg (6 cwt)	60ml

Above 300 kg give 10ml per 50kg
Sheep: 5.0 mg oxfendazole per kg bodyweight.

Bodyweight	Dose
Up to 14 kg (30 lb)	2.5 ml
15 - 27 kg (31 - 60 lb)	5.0 ml
28 - 40 kg (61 - 90 lb)	7.5 ml
41 - 54 kg (91 - 120 lb)	10.0 ml
55 - 67 kg (121 - 150 lb)	12.5 ml
Over 67kg (150lb)	15.0 ml

For oral administration only. Give the recommended dose by mouth using standard dosing equipment. After treatment, animals should be moved to clean pasture in order to prevent re-infection. Where this is not done, regular re-treatment may be necessary.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle should not be slaughtered for human consumption until 14 days after treatment.
Sheep should not be slaughtered for human consumption until 10 days after treatment.
Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from a cow after 5 days from the last treatment.
Not to be used in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antihelmintics, oxfendazole.

ATCvet Code: QP52AC02

5.1 Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphinyl-1-H-benzimidazole-2-yl] carbamate), belongs to a class of compounds, the benzimidazoles.

The Benzimidazoles possess anti-mitotic properties, and this action is related to their capacity to bind to tubulin leading to inhibition of formation of microtubules. This, in turn, leads to disruption of cell division. Eventually cell lysis and disintegration occur. Oxfendazole may concentrate preferentially in intestinal cells of parasites to exert its toxic effects initially and principally at this site. Similar effects do not occur in host cells, possibly because of differential binding characteristics. The disruption of parasite metabolic processes, and the effects of oxfendazole on enzymes of helminth parasites, involves inhibition of glucose and sodium uptake, reduced muscle glycogen content, uncoupling of oxidative phosphorylation and inhibition of malate dehydrogenase and fumarate reductase.

5.2 Pharmacokinetic properties

A relationship exists between plasma concentrations of active anthelmintic metabolites, the duration of high plasma metabolite concentrations and anthelmintic efficacy.

Oxfendazole is a sulphoxide identical to the sulphoxide metabolite of fenbendazole, both are known to be anthelmintically active and metabolically interconvertible.

Reduction of oxfendazole to fenbendazole occurs in the ruminal fluid while oxidation of fenbendazole to oxfendazole is carried out by hepatic microsomal enzymes in the liver. Much of fenbendazole's anthelmintic activity is attributed to oxfendazole, the latter being much more potent.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Parahydroxybenzoate
Trisodium Citrate
Citric Acid
Sodium Metabisulphite
Di Sodium Edetate
Polysorbate 80
Xanthan Gum
Simethicone Emulsion
Purified Water

6.2 Incompatibilities

None.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Store below 25°C.
Protect from frost and light.

6.5 Nature and composition of immediate packaging

Parafend will be presented in 500 ml, 1.0 L, 2.5 L, 5 L and 10 L multi-dose polyethylene containers with polyethylene closures. Not all pack sizes may be marketed.

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 guidelines for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down, BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/059/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th July 2009

10 DATE OF REVISION OF THE TEXT