

**IRISH MEDICINES BOARD ACT 1995**

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

**(S.I. No. 786 of 2007)**

VPA: **10999/061/001**

Case No: 7005216

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 9.06% 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 9.06% Oral Suspension

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Oxfendazole 9.06 % w/v

Excipients:

Sodium Methyl Parahydroxybenzoate 0.18 % w/v  
(preservative)

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 is a broad spectrum anthelmintic for the treatment and control of mature and developing immature gastrointestinal roundworms and lungworms and also tapeworms in cattle and sheep. Parafend 9.06% 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 9.06% 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.

## 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.

(1ml contains 90.6mg oxfendazole)

Bodyweight	Dose	No. of Doses per pack
100kg (2 cwt)	5ml	100
150kg (3 cwt)	7.5ml	66
200kg (4 cwt)	10ml	50
250kg (5cwt)	12.5ml	40
300kg (6 cwt)	15ml	33

Above 300 kg give 2.5ml per 50kg bodyweight.

Sheep: 5.0 mg oxfendazole per kg bodyweight.

(1ml contains 90.6mg oxfendazole)

Bodyweight	Dose	No. of Doses per pack
11-20 kg (23-44 lb)	1.0ml	500
21-30 kg (45 - 66 lb)	1.5ml	333
31 - 40 kg (67 - 88 lb)	2.0ml	250
41 - 50 kg (89 - 110 lb)	2.5ml	200
51 - 60 kg (111 - 132 lb)	3.0ml	166
61 - 70 kg (133 - 154 lb)	3.5ml	142
71 - 80 kg (155 - 176 lb)	4.0ml	125
Over 80kg (over 176lb)	5.0 ml	100

*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)

Animals should not be slaughtered for human consumption until 14 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: Anthelmintics, oxfendazole.

ATCvet Code: QP52AC02

### 5.1 Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphonyl-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, Anhydrous  
Sodium Metabisulphite  
Disodium Edetate  
Polysorbate 80  
Xanthan Gum  
Simethicone Emulsion  
Purified Water

### 6.2 Incompatibilities

None known.

### 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 250ml, 500ml, 1.0L, 2.5L and 5L 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,  
N. Ireland.

### **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10999/061/001

### **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

9<sup>th</sup> Febraury 2009

### **10 DATE OF REVISION OF THE TEXT**