IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/066/001**
Case No: 7001684

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 5% SC

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 **06/02/2007**.

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 5% SC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredients of Parafend 5.0% SC are Oxfendazole 50.0 mg/ml, elemental selenium 1.1 mg/ml (as anhydrous sodium selenate) and elemental cobalt 3.69 mg/ml (as cobalt sulphate). Sodium Methyl Hydroxybenzoate 0.18 % w/v is included as a preservative.

For a full list of excipients see 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 mature and developing gastro-intestinal roundworms, lungworms and also tapeworms in sheep. Parafend 5% SC is ovicidal for strongyle eggs.

For the treatment of sheep infested with benzimidazole susceptible species of:

Gastrointestinal roundworms:

Ostertagia spp.
Haemonchus spp.
Nematodirus spp.
Trichostrongylus spp.
Cooperia spp.
Oesophagostomum spp.
Chabertia spp.
Capillaria spp.
Trichuris spp.

Lungworms:

Dictyocaulus spp.

Tapeworms:

Moniezia spp.

It is effective against inhibited/arrested larvae of *Nematodirus* spp. and benzimidazole susceptible *Haemonchus* spp. and *Ostertagia* spp..

Selenium and cobalt are included as nutritional supplements.

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

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

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.
Shake container before use.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant and lactating animals.
Milk taken from treated sheep should not be used for consumption.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Sheep: 5.0 mg oxfendazole per kg bodyweight.

Bodyweight	Dose
11 – 20 kg (23 - 44 lb)	2.0 ml
21 – 30 kg (45 - 66 lb)	3.0 ml
31 – 40 kg (67 - 88 lb)	4.0 ml
41 – 50 kg (89 - 110 lb)	5.0 ml
51 – 60 kg (111 - 132 lb)	6.0 ml
61 – 70 kg (133 - 154 lb)	7.0 ml
71 – 80 kg (155 - 176 lb)	8.0 ml
Over 80 kg (over 176 lb)	1 ml per 10 kg bodyweight

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

None known.

4.11 Withdrawal Period(s)

Meat: Animals intended for human consumption may be slaughtered after 14 days following treatment.

Milk: Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

Oxfendazole is believed to act by irreversibly inhibiting glucose uptake by the parasites resulting in depletion of the parasites energy sources, glycogen and ATP, and their consequent death and expulsion.

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.

Cobalt has been recognised as an essential dietary component for ruminants since the 1930's. It is peculiar as an essential trace element in ruminant nutrition in that it is stored in the body in limited amounts only and hence symptoms of deficiency can occur very rapidly. The effect of Cobalt in the rumen is to participate in the production of Vitamin B_{12} (produced by ruminal micro-organisms) and compared to omnivores the requirement for Vitamin B_{12} is very much higher.

The biochemical role of Selenium is as a component of the enzyme glutathione peroxidase (GSH-PX). The exact role of GSH-PX in mammalian cells is not fully understood but it is thought to act by protecting cells from oxidizing agents which are capable of irreversibly denaturing essential cellular proteins which leads to degeneration and necrosis, resulting in muscular weakness and white muscle disease commonly associated with Selenium deficiency. It is believed that a deficiency in Selenium can cause a decrease in the humoral response of animals to vaccination and increase the susceptibility of animals to disease. The symptoms are most pronounced in young fast growing animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Hydroxybenzoate
Trisodium Citrate Dihydrate
Citric Acid (Anhydrous)
Sodium Metabisulphite
Disodium Edetate
Polysorbate 80
Xanthan Gum
Simethicone
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

Do not store above 25^{o}C. Protect from light. Protect from frost.

6.5 Nature and composition of immediate packaging

Parafend 5% SC will be presented in 500ml, 1.0 L, 2.5 L and 5 L polyethylene multi-dose containers sealed with plastic screw cap fitted with plastic coated paper washers.

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

Norbrook Laboratories Limited
Station Works
Camlough Road
NEWRY
Co. Down, BT35 6JP

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/066/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th February 2007

10 DATE OF REVISION OF THE TEXT