SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parafend 2.265% w/v Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

The active ingredient of Parafend is Oxfendazole 2.265 % w/v

Excipients:

Sodium methyl parahydroxybenzoate 1.8 mg/ml as an antimicrobial preservative and Sodium metabisulphite 1.5 mg/ml as antioxidant

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension
An off white to white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in sheep. Ovicidal for strongyle eggs.

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

GASTROINTESTINAL ROUNDWORMS:
Ostertagia spp, *Haemonchus* spp, *Nematodirus* spp, *Trichostrongylus* spp, *Cooperia* spp, *Oesophagostomum* spp and *Chabertia* spp.

Also provides useful control of *Trichuris* spp.

LUNGWORMS:
Dictyocaulus spp

TAPEWORMS:
Moniezia spp

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

4.3 Contraindications

None

4.4 Special Warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Under dosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any)

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test (s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles has been reported in *Teladorsagia, Haemonchus, Cooperia and Trichostongylus* species in small ruminants. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

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.

Shake container before use.

Do not exceed the stated dose.

For oral use only

The bodyweight of animals should be assessed as accurately as possible before calculating the dosage.
Veterinary advice should be sought (a) on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing; (b) if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

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. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None recorded.

4.7 Use during pregnancy, lactation or lay

The product 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

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Shake container before use.
Do not mix with other products.

Sheep: 5.0 mg oxfendazole per kg bodyweight.

Bodyweight	*Dose*
Up to 9 kg (approx 20 lb)	2ml
10 - 13.5 kg (22 to 30 lb)	3ml
14 - 18 kg (31 to 40 lb)	4ml
19 - 22.5 kg (42 to 50 lb)	5ml
23 - 27 kg (51 to 59 lb)	6ml
28 - 31.5 kg (62 to 69 lb)	7ml
32 - 36 kg (71 to 79 lb)	8ml
37 - 40.5 kg (80 to 89 lb)	9ml
41 - 45 kg (90 to 99 lb)	10 ml

Over 45 kg give 3.0ml for each additional 14 kg bodyweight. (1ml/4.5kg)

For oral administration only. Give the recommended dose by mouth using standard dosing equipment. Dosing may be repeated at required intervals (see 4.5).

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

Benzimidazoles have a wide margin of safety.

4.11 Withdrawal period

Sheep – Meat: 10 days

Not for use in sheep producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics

ATC Vet Code: QP52AC02

5.1 Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphinyl-1-H-benzimidazole-2yl] 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.

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
Sodium metabisulphite
Sodium Citrate dihydrate
Citric acid anhydrous
Disodium edetate
Polysorbate 80
Xanthan gum
Semitcone
Water, Purified

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
0.5L, 1.0L, 2.5L & 5L – 4 years.
10.0L – 2 years.

6.4 Special precautions for storage

Do not store above 25ºC. Protect from frost. Protect from light.

6.5 Nature and composition of immediate packaging

Presented in 0.5 L, 1.0 L, 2.5 L, 5 L and 10 L white high density polyethylene flexipacks or rigid packs closed with white high density polyethylene screw caps with polyethylene coated plastic washers.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Do not contaminate ponds, waterways or ditches with product or used containers.

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4119

9. DATE OF FIRST AUTHORISATION

27th July 1994

10. DATE OF REVISION OF THE TEXT

August 2010