SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenzol 5.0% w/v Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	**% w/v**
Fenbendazole	5.000
Excipients	
Sodium Methylhydroxybenzoate	0.199
Sodium Propylhydroxybenzoate	0.022

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.
A white to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep

4.2 Indications for use, specifying the target species

The product is a broad spectrum anthelmintic for the control of mature and developing immature forms of the following species of gastrointestinal roundworms, tapeworms and lungworms in cattle and sheep. It is ovicidal for strongyle eggs.

In cattle it is effective against the following parasites:

Gastrointestinal Roundworms:

Haemonchus spp.,
Ostertagia spp.,
Trichostrongylus spp.,
Cooperia spp.,
Nematodirus spp.,
Bunostomum spp.,
Trichuris spp.,
Strongyloides spp.,
Oesophagostomum spp.,

Lungworms:

Dictyocaulus spp.

The product is usually effective against inhibited larvae of *Ostertagia* spp. and in the control of *Moniezia* spp. of tapeworm in cattle.

In sheep it is effective against benzimidazole susceptible strains of the following parasites.

GASTROINTESTINAL ROUNDWORMS:

Haemonchus spp.,
Ostertagia spp.,
Trichostrongylus spp.,
Cooperia spp.,
Nematodirus spp.,
Strongyloides spp.,
Oesophagostomum spp.,
Chabertia spp.,
Bunostomum spp.,

LUNGWORMS:

Dictyocalus spp.

The product is usually effective in the control of *Moniezia* spp. of tapeworm and provides useful control of *Trichuris* spp in sheep.

4.3 Contraindications

None known.

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.
- Underdosing, 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 (which includes oxfendazole) has been reported in *Teladorsagia, Haemonchus, Cooperia and Trichostongylus* species in small ruminants in a number of countries, including the EU. 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.

The bodyweight of animals should be assessed as accurately as possible before calculating the dose. As with other anthelmintics 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 resistence 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 product to the 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

Safe when used at the recommended dose rate during pregnancy and lactation.

4.8 Interactions with other medicinal products and other forms of interaction

None.

4.9 Amount to be administered and administration route

Cattle: 7.5 mg fenbendazole per kg bodyweight.
(7.5 ml per 50 kg (1 cwt) bodyweight)

Bodyweight	Dose
50 kg (1 cwt)	7.5 ml
100 kg (2 cwt)	15 ml
150 kg (3 cwt)	22.5 ml
200 kg (4 cwt)	30 ml
250 kg (5 cwt)	37.5 ml
300 kg (6 cwt)	45 ml

Above 300 kg give a further 7.5 ml for each additional 50 kg bodyweight.

Sheep: 5.0 mg fenbendazole per kg bodyweight.
(1 ml per 10 kg (22lb) bodyweight)

Bodyweight	Dose
Up to 10 kg (22lb)	1.0 ml
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

Above 80 kg (above 176 lb) give a further 1.0 ml for each additional 10 kg bodyweight.

For oral administration only. Give the recommended dose by mouth using standard dosing equipment. Dosing may be repeated at required intervals. Do not mix with other products.

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

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

Benzimidazoles possess a wide margin of target species safety.

4.11 Withdrawal periods

Cattle (meat & offal): 12 days
Sheep (meat & offal): 14 days
Cattle (milk): 5 days
Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Benzimidazoles and pro-benzimidazoles

ATCvet Code: QP52AC13

5.1 Pharmacodynamic properties

Fenbendazole, [5-phenylthio)-2-benzimidazole-carbamic] acid methyl ester, 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. Fenbendazole 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 interconvertable.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Parahydroxybenzoate
Sodium Propyl Parahydroxybenzoate
Sodium Citrate Dihydrate
Citric Acid Anhydrous
Silica Colloidal Anhydrous
Carmellose Sodium
Povidone K30
Sodium Hydroxide
Hydrochloric Acid
Water Purified

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 note store above 25°C. Protect from light. Protect from frost.

6.5 Nature and composition of immediate packaging

500 ml, 1, 2.5, 5 litre white high density polyethylene flexi pack with high density polyethylene cap (screw fit) over an aluminium seal.
2.5 litre, 5 litre white high density polyethylene jerrican with polypropylene cap (screw fit) over an aluminium seal.
500 ml, 1 litre, 10 litre white high density polyethylene jerrican with polypropylene cap (screw fit) over an aluminium seal.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4128

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th March 1995

10. DATE OF REVISION OF THE TEXT

June 2010