

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenzol 5% Oral Suspension Worm Drench for Cattle and Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Fenbendazole	50.00 mg
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Excipients:

Methyl Parahydroxybenzoate (E218)	1.740 mg
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Propyl Parahydroxybenzoate (E216)	0.196 mg
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For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

An off-white oral 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 stages of the following species of gastrointestinal round worms and lungworms in cattle and sheep. The product is ovicidal for strongyle eggs.

Cattle:

For the treatment of cattle infected with benzimidazole - susceptible strains of the following species:

GASTRO-INTESTINAL ROUNDWORMS

<i>Haemonchus</i> spp.	<i>Trichuris</i> spp.
<i>Ostertagia</i> spp.	<i>Strongyloides</i> spp.
<i>Trichostrongylus</i> spp.	<i>Oesophagostomum</i> spp.
<i>Cooperia</i> spp.	
<i>Nematodirus</i> spp.	
<i>Bunostomum</i> spp.	

LUNGWORMS:

Dictyocalus spp.

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

Sheep:

For the treatment of sheep infected with Benzimidazole susceptible strains of the following species.

GASTROINTESTINAL ROUNDWORMS:

<i>Haemonchus</i> spp.	<i>Strongyloides</i> spp.
<i>Ostertagia</i> spp.	<i>Oesophagostomum</i> spp.
<i>Trichostrongylus</i> spp.	<i>Chabertia</i> spp.
<i>Cooperia</i> spp.	
<i>Nematodirus</i> spp.	
<i>Bunostomum</i> spp.	

LUNGWORMS:

Dictyocaulus spp.

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

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

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.

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 resistance developing; (b) if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance may be present.

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 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, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Cattle: 7.5 mg fenbendazole per kg bodyweight.
(7.5 ml of the product 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 of the product per 10 kg (22 lb) bodyweight)

Bodyweight	Dose
Up to 10 kg (22 lb)	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. After treatment, animals should be moved to clean pasture in order to prevent reinfection. 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 intended for human consumption must not be taken during treatment.

Milk intended for human consumption may only be taken from a cow after 96 hours from the last treatment.

Not to be used in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, 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.

Fenbendazole 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 sulfoxide identical to the sulfoxide metabolite of fenbendazole, both are known to be anthelmintically active and metabolically interconvertible.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Sodium Citrate
Anhydrous Citric Acid
Silicon Dioxide
Carmellose Sodium
Povidone
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C.

Protect from frost and light.

6.5 Nature and composition of immediate packaging

The product will be presented in 0.5 L, 1 L, 2.5 L and 5 L high density polyethylene multidose containers with high density polyethylene or polypropylene closures.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/063/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd November 2010

10 DATE OF REVISION OF THE TEXT