Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT
Fenbenor 2.5% w/v Oral Drench.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Fenbendazole	25.0 mg

Excipients

Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Sodium Metabisulphite	1.0 mg

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
Sheep.

4.2 Indications for use, specifying the target species
Fenbenor 2.5% w/v Drench is a broad spectrum anthelmintic for control of benzimidazole susceptible mature and developing immature forms of the following nematodes of the gastrointestinal and respiratory tracts of sheep.

For the treatment of sheep infected with:
Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.
Trichuris spp.
Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus spp
Moniezia spp.

4.3 Contraindications
Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

When dosing sheep, care must be taken not to damage the mouth or pharyngeal region with drenching equipment.
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
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Sheep have been reported to be sensitive to benzimidazoles during the first quarter of gestation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration in sheep.
Shake well before use.
The recommended treatment dose is 5 mg Fenbendazole per kg bodyweight.
Practical dosage recommendations are as follows:

Bodyweight (kg)	Dose (ml)	Number of doses per pack
10	2.0	500
50	10.0	100

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

Not applicable.

4.11 Withdrawal Period(s)

Sheep must not be slaughtered for human consumption during treatment or for 28 days thereafter.
This product should not be used in ewes producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Anthelmintic, fenbendazole,

ATCvet Code: QP52AC13.

Summary presentation of the active ingredient
Fenbendazole is an anthelmintic belonging to the benzimidazole group which acts by locking fumarate reductase which results in the inhibition of the formation of adenosine triphosphate (involved in mitochondrial energy).

5.1 Pharmacodynamic properties
Fenbendazole, like many benzimidazoles, blocks fumarate reductase which results in the inhibition of the formation of adenosine triphosphate (involved in mitochondrial energy). There is also evidence that it inhibits glucose uptake and therefore increases glycogen utilization and depletes the worm's glycogen reserves. The overall effect of this action is to effectively starve the parasite to death. Furthermore this action results in the detachment of the parasites but in the case of intestinal helminths this detachment does not result in loss of contact with the drug whereas in the case of the liver fluke such detachment would reduce such contact. This probably explains its limited effect on the liver fluke and the good effect on intestinal helminths.

5.2 Pharmacokinetic properties
Fenbendazole is poorly soluble in water and consequently is poorly absorbed; something which is reflected in the relatively low plasma levels. The scheme for the known metabolic pathways is given by Short, Flory, Hsieh and Barker (1988) together with the relative rates of breakdown in various species. The main breakdown products are the sulphoxide (oxfendazole) and sulphone.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Polysorbate 80
Sodium metabisulphite
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Sodium Citrate
Citric Acid
Simeticone emulsion
Xanthan Gum
Purified Water

6.2 Incompatibilities
None known.

6.3 Shelf-life
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage
Do not store above 25^{o}C.
Do not freeze.

6.5 Nature and composition of immediate packaging

1 L (jerrican, flat bottom flexi), 2.5 L (jerrican, back pack), 5 L (jerrican) HDPE white rigid containers closed with a ~~HDPP~~ polypropylene screw cap with an ~~wood pulp PVDC~~induction heat seal liner..
Not all pack sizes may be marketed.

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

Empty containers must be rinsed with water before disposal.
Dispose of used containers safely.
Do not contaminate ponds, waterways or ditches with product or used containers.
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

Pharvet (Ireland) Ltd.,
29 Cookstown Industrial Estate,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10462/002/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd August 2007

10 DATE OF REVISION OF THE TEXT

~~October 2012~~xxx