Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT
Fenbenor 10 % Oral Drench.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Fenbendazole	100 mg

Excipients

Methyl Parahydroxybenzoate (E218)	2 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
SodiumMetabisulphite	1 mg

3 PHARMACEUTICAL FORM
Oral suspension.
A white to off white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species
Cattle.

4.2 Indications for use, specifying the target species
A broad spectrum anthelmintic for control of benzimidazole susceptible mature and developing forms of the following nematodes of the gastrointestinal and respiratory tracts of cattle.
Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.
Trichuris spp.
Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus spp.

In cattle the product is usually effective against inhibited larvae of *Ostertagia* and also for the control of tapeworms *Moniezia* spp.

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

4.4 Special warnings for each target species
None.

4.5 Special precautions for use

Special precaution(s) for use in animals
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 disease, nutritional disturbances or anthelmintic resistance may be involved.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact with the skin should be kept to a minimum.
Wash hands after use.
Wear suitable protective clothing including impermeable rubber gloves.

4.6 Adverse reactions (frequency and seriousness)
None known

4.7 Use during pregnancy, lactation or lay
This 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
The recommended therapeutic dose of fenbendazole is 7.5 mg/kg bodyweight.
For oral administration in cattle.
Shake well before use.
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.
Practical dosage recommendations:

Bodyweight (kg)	Dose	(ml)
To - 65 kg	5	ml
66 - 125 kg	10	ml
126 - 200 kg	15	ml
201 - 270 kg	20	ml
271 - 340 kg	25	ml
341 - 400 kg	30	ml

Above 400 kg 3.75 ml per 50kg.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
None.

4.11 Withdrawal Period(s)
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.
Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 120 hours (5 days) from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Fenbendazole is an anthelmintic belonging to the benzimidazole group which acts by blocking fumarate reductase, which results in the inhibition of the formation of adenosine triphosphate (involved in mitochondrial energy). The overall effect of this action is to effectively starve the parasite to death.

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 main metabolites 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
3 years.

6.4 Special precautions for storage
Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging
1 L (jerrican, flat bottom flexi), 2.5 L (jerrican, back pack) and 5 L (jerrican) HDPE white rigid containers closed with a polypropylene screw-cap with an 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.
Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10462/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th July 2006

10 DATE OF REVISION OF THE TEXT

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