Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenafluke 5% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substances

Fenbendazole	50.00 mg
Rafoxanide	50.00 mg

Excipients

Propyl parahydroxybenzoate (E216)	0.10 mg
Methyl parahydroxybenzoate (E218)	1.00 mg
Quinoline yellow (E104)	0.09 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.
A pale, lemon suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Fenafluke 5% Oral Drench permits a three way activity against Fluke, Lungworms and Stomach Worms in Cattle and Sheep. It is a broad spectrum anthelmintic for the treatment of benzimidazole susceptible mature and immature stages of nematodes and cestodes of the gastrointestinal and respiratory tracts of cattle and sheep.
Rafoxanide is active against immature and mature *Fasciola hepatica* (mature and immature over 8 weeks of age).

Cattle and Sheep:

Haemonchus sp.
Ostertagia sp.
Trichostrongylus sp.
Cooperia sp.
Nematodirus sp.
Bunostomum sp.
Trichuris sp.
Strongyloides sp.
Oesophagostomum sp.
Dictyocaulus sp.
Moniezia sp.
Fasciola hepatica (mature and immature over 8 weeks of age).

The product has a good therapeutic effect against type II Ostertagiasis.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

Where a dosing gun is used to administer the product care must be taken to avoid the occurrence of dosing gun pharyngitis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Fenbendazole and rafoxanide are safe for use during pregnancy.
See section 4.11.

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 cattle and sheep.

For sheep, the recommended therapeutic dose is 7.5 mg fenbendazole and 7.5 mg rafoxanide per kilogram bodyweight. For cattle, the recommended therapeutic dose is 11.25 mg fenbendazole and 11.25 mg rafoxanide per kilogram bodyweight.

Shake well before use
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.
Practical dosage recommendations are as follows:

Bodyweight (Kg)	**Dose (ml)**
CATTLE	
50	11.25
100	22.5
400	90.0
> 400 kg	11.25 ml/50 kg
SHEEP	
10	1.5
50	7.5

At 2 months after housing, when dosing cattle for worms and adult fluke, a lowerdose of 7.5 mg/kg can be used i.e. 7.5 ml per 50 kg bodyweight, 30ml per 200 kg or 75 ml per 500 kg.

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

Fenafluke 5% Oral Drench is well tolerated in cattle at three times the recommended dosage.

4.11Withdrawal Period(s)

Edible tissues from slaughtered animal: 60 days
Milk:
Not authorised for use in animals producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Fenafluke 5% Oral Drench is a broad spectrum anthelmintic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan Gum (E415)
Quinoline Yellow (E104)
Simethicone Emulsion
Propyl Parahydroxybenzoate (E216)
Methyl Parahydroxybenzoate (E218)
Tween 80
Sodium citrate (E331)
Sodium metabisulphite (E223)
Citric acid monohydrate
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
White HDPE containers: Three years

6.4 Special precautions for storage

Store below 25°C.
Protect from light and frost.

6.5 Nature and composition of immediate packaging

1L (jerrican and flexipack), 2.5L (jerrican and backpack) or 5L (jerrican) HDPE white 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

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 10462/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th September 2008

10 DATE OF REVISION OF THE TEXT

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