Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panafluke Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Rafoxanide	4.5% w/v
Fenbendazole	3.0% w/v

Other Ingredients

Methyl Parahydroxybenzoate	0.2% w/v
Propyl Parahydroxybenzoate	0.02% w/v
Chlorophyll WS 1 (E141)	0.15% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep.

4.2 Indications for use, specifying the target species

Panafluke is effective against mature and developing immature stages of all major stomach and bowel worms including *Haemonchus, Ostertagia, Cooperia, Trichostrongylus, Nematodirus, Bunostomum, Trichuris, Strongyloides, Oesophagostomum* and *Dictyocaulus* species, and also *Chabertia* and *Moniezia* in sheep and *Capillaria* in cattle. It is also active against roundworm eggs and inhibited *Ostertagia* (winter scours). Panafluke is highly effective against mature fluke in cattle and sheep and is also 83% effective against 4-week-old immature fluke in sheep.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

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 precaution(s) for use in animals

Shake well before use.

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

When using do not eat, drink or smoke. Wash hands and exposed skin before meals and after work. Remove immediately any contaminated clothing. Wash splashes from eyes and skin immediately.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Panafluke may be safely used 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

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.
For oral use only at a dose rate, for cattle and sheep, of 11.25mg Rafoxanide per kg bodyweight and 7.5 mg Fenbendazole per kg bodyweight equivalent to 2.5 ml Panafluke per 10 kg bodyweight.

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

No specific signs.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 60 days from the last treatment.

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

Phamacotherapeutic group: Anthelmintics.
ATCvet code: QP52A

5.1 Pharmacodynamic properties

Panafluke contains two active ingredients, Rafoxanide and Fenbendazole. Rafoxanide is a halogenated salicylanilide, which was developed in 1969. Its principal use is as an adulticide for both F.hepatica and F.gigantica, but it also has the advantage of having respectable efficacy for immature flukes. Rafoxanide acts by uncoupling oxidative phosphorylation. Liver flukes treated in vivo or in vitro with rafoxanide show indirect evidence of uncoupling, including reduced ATP levels, decreased glycogen content and accumulation of succinate. Rafoxanide also binds strongly to plasma proteins and is inactive until ingested by the parasite and separated from the plasma albumin by digestion. For this reason rafoxanide does not affect the host's mitochondria in vivo. Only blood-sucking nematodes and flukes residing in the bile, through which salicylanilides are excreted from the host's body, are susceptible to rafoxanide.

Fenbendazole is a member of the benzimidazole family of anthelmintics. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting in the preferential toxicity of fenbendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Citric Acid Monohydrate
Disodium Phosphate Dodecahydrate
Colloidal Silica Anhydrous
Chlorophyll WS 1 (E141)
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion
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°C.

6.5 Nature and composition of immediate packaging

High density polythene containers with polypropylene closures, containing 1L, 2.5L or 5L.
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

Intervet Ireland Limited,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/120/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd March 2009

10 DATE OF REVISION OF THE TEXT

May 2013