Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur SC 2.5% w/v Oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Fenbendazole	25.0	mg

Excipients

Selenium (as sodium selenite)	0.4	mg
Cobalt (as cobalt sulphate heptahydrate)	0.94	mg
Sodium methyl parahydroxybenzoate	2.0	mg
Sodium propyl parahydroxybenzoate	0.2	mg
Benzyl Alcohol	4.8	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of sheep infected with mature and developing immature forms of nematodes of the gastro-intestinal and respiratory tracts. Panacur also has an ovicidal effect on nematode eggs.

Sheep: For the treatment of sheep infected with benzimidazole susceptible:

Ostertagia spp.	*Haemonchus* spp.
Trichostrongylus spp.	*Nematodirus* spp.
Cooperia spp.	*Oesophagostomum* spp.
Chabertia spp.	*Bunostomum* spp.
Strongyloides spp.	*Dictyocaulus filaria*

Panacur is usually effective against *Moniezia* spp. of tapeworm and may have useful but variable efficacy against *Trichuris* spp.

The selenium and cobalt in this product are trace elements of use as nutritional supplements.

4.3 Contraindications

Do not use in sheep producing milk for human consumption. Do not administer to animals with known hypersensitivity to the active ingredient.

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 body weight, 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 test(s) 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

The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur. In cases of doubt, consult your veterinary surgeon.

As with all sheep drenches, care must be taken not to injure the pharyngeal region with drenching equipment.

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. Wear suitable protective clothing including impermeable rubber gloves.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant ewes.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.9 Amounts to be administered and administration route

For oral administration only.
No dietary control is required before or after treatment.

Sheep: Administer orally 1 ml Panacur SC 2.5% Oral Suspension per 5 kg bodyweight.
(= 5 mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

Up to 5 kg	1 ml
5 to 10 kg	2 ml
11 to 20 kg	4 ml
21 to 30 kg	6 ml
31 to 40 kg	8 ml
41 to 50 kg	10 ml
51 to 60 kg	12 ml
61 to 70 kg	14 ml

Above 70 kg, an extra 1 ml is required for each additional 5 kg bodyweight.

Panacur SC 2.5% Oral Suspension is best administered to sheep with the Panacur 20 ml Automatic Drencher but other calibrated dosing guns or drenching equipment may also be used. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Treatment should be repeated every 6-8 weeks during the grazing season.

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

No special actions required.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Meat and offal: 14 days
Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances
ATCvet code: QP52AC13

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic belonging to the benzimidazole carbamates group. It acts by interfering with the energy metabolism of the nematode. The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes. The anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

5.2 Pharmacokinetic properties

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. The half life of fenbendazole in serum after oral application of the recommended dose in cattle is 10-18 hours, in sheep 21-33 hours and in pigs 10 hours. Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a small extent in the urine and milk. Fenbendazole is metabolised to its sulphoxide then to sulphone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Selenium (as sodium selenite)
Cobalt (as cobalt sulphate heptahydrate)
Sodium methyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Benzyl alcohol
Colloidal Silicone Dioxide
Carmellose Sodium
Povidone 25000
Sodium Acetate trihydrate
Glacial Acetic Acid
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.
Protect from freezing.

6.5 Nature and composition of immediate packaging

1, 2.5, 5 litre multidose polyethylene containers closed with a thermosealed cap with PE layered join.
Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/114/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

May 2012