IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/110/001**
Case No: 7005957

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Panacur SC 10% w/v Oral Suspension

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur SC 10% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance(s):		
Fenbendazole	100.00	mg
Excipients		
Cobalt (as Cobalt sulphate heptahydrate)	2.5	mg
Selenium (as Sodium selenate)	2.0	mg
Sodium methyl parahydroxybenzoate	1.88	mg
Sodium propyl parahydroxybenzoate	0.205	mg
Benzyl Alcohol	4.57	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of cattle 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.

Cattle: for the treatment of cattle infected with adult and immature stages of:

Ostertagia spp.	*Cooperia* spp.
Trichostrongylus spp.	*Nematodirus* spp.
Haemonchus spp.	*Oesophagostomum* spp.
Bunostomum spp.	*Strongyloides* spp.
Trichuris spp.	*Dictyocaulus viviparus*

When used at the recommended dose and time, Panacur is effective against inhibited larvae of *Ostertagia* spp. and against *Moniezia* spp. of tapeworm.

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

4.3 Contraindications

Do not administer other Cobalt and Selenium supplements with this product unless specifically advised by your Veterinary Surgeon.
Do not administer to animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

Concurrent administration of ionophores and Panacur SC 10% may lead to an increased risk of selenium toxicity.

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

This product contains considerably larger amounts of cobalt and selenium than contained in existing mineralised formulations of Panacur. This should be taken into consideration when deciding on frequency of treatment. The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur.

Not recommended for species other than cattle.

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 animals.

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.

Administer orally approximately 1 ml Panacur SC 10% Suspension per 13 kg bodyweight.
(= 7.5 mg fenbendazole/kg bodyweight)
Practical dosage recommendations:

65 kg	5 ml
135 kg	10 ml
200 kg	15 ml
265 kg	20 ml
335 kg	25 ml
400 kg	30 ml

Above 400 kg, an extra 2.5 ml are required for each additional 33 kg bodyweight.

Panacur SC 10% Suspension is best administered to cattle with the Panacur 20 ml Automatic Drencher. 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
Milk: 4 days

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

Colloidal Anhydrous Silica
Sodium carboxymethylcellulose
Povidone
Sodium Methyl Hydroxybenzoate
Sodium Propyl Hydroxybenzoate
Sodium Acetate
Glacial Acetic Acid
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from freezing.

6.5 Nature and composition of immediate packaging

250 ml, 1L, 2.5L and 5L opaque high density polyethylene containers with a tamperproof polyethylene coated aluminium foil seal and polypropylene screw cap. Not all pack sizes may be marketed.

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

Dispose of unused containers safely. Do not contaminate ponds, waterways or ditches with product or used container. Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/110/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT