IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10019/010/001**
Case No: 7006134

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:

Pfizer Healthcare Ireland

Ringaskiddy, **Co. Cork**, **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:

STRONGID-P Granules 5.7 g/sachet

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

STRONGID-P Granules 5.7 g/sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active Substance

Pyrantel embonate 5.7 g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules

Pale yellow to buff free-flowing granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, ponies and foals over four weeks of age and donkeys.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for use in horses and donkeys for the control and treatment of adult infections of large and small strongyles, *Oxyuris*, *Parascaris* and *Anoplocephala perfoliata.*

Effective against benzimidazole resistant strains of small strongyles.

4.3 Contraindications

Do not use in 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.
- Under-dosing which may be due to under-estimation of bodyweight, mis-administration of the product or lack of calibration of the dosing device (if any).

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.

Resistance to pyrantel has been reported in cyathostomes in horses in a number of countries, including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

Stomach-tube administration: normal precautions should be observed.
Only to be carried out by a veterinary surgeon.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with skin. Wash hands and any other parts of the body which come into contact with the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

May be used in pregnant and/or lactating mares.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. Accuracy of the dosing device should be checked.

Administration: Strongid-P Granules may be given in the feed or by stomach-tube in horses, ponies, donkeys and foals over four weeks of age.
It is not necessary to withhold any feed prior to administration.
Use medicated feed or suspension immediately after mixing.
Feed: granules should be dispersed evenly in the feed, preferably a reduced quantity of feed, to ensure consumption of a full drug dose. Any unconsumed medicated feed should be discarded.
Stomach Tube: Strongid-P Granules suspended in warm water may be administered by a veterinary surgeon via a stomach-tube. Add the required amount of Strongid-P Granules to warm water and stir immediately before use.

Dosage: For the control and treatment of strongyles (including benzimidazole resistant worms), *Oxyuris* and *Parascaris* (Redworms, Seatworm/Pinworm and Roundworm). Strongid-P should be used at a dose rate of 19 mg pyrantel embonate per kg bodyweight.
Sachet pack: 1 sachet per 300 kg (660lb) bodyweight. Each sachet contains 7.43 g Strongid-P granules (5.7 g pyrantel embonate).
1.5 kg pack: 1 level measure per 90 kg (200lb) bodyweight. One level measure contains approximately 2.2 g Strongid-P granules (1.7 g pyrantel embonate). For accuracy level the measure with a knife blade.

Dosage For Tapeworm:
For the control and treatment of *Anoplocephala perfoliata* (tapeworm) the dose rate is 38 mg per kg bodyweight, that is twice the dose rate for strongyles.
Sachet pack: 1 sachet per 150 kg (330lb) bodyweight.

1.5 kg pack : 1 level measure per 45 kg (100 lb) bodyweight.

Dosing Programmes
Strongyles (including benzimidazole resistant worms), O*xyuris* and *Parascaris.*
Foals: one to eight months of age - dose every four weeks.
Horses and donkeys: over eight months of age - routinely dose every six to eight weeks but during the summer and autumn when at grass, dose every four to six weeks. Always dose three to four days before turning out after in-wintering.
Suckler mares: reduction of strongyle challenge to the suckling foal at pasture can be achieved by using clean pasture (re-seeded, or not grazed by horses the previous year), dosing the mare three to four days before turning out and then at intervals of two to four weeks until the end of autumn. Ideally mares with foals should go out to clean pasture.

Anoplocephala perfoliata (tapeworm):
The need for retreatment may vary but if considered necessary after examination of dung for eggs, it should be carried out after an interval of six weeks.

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

The product has an extremely wide safety margin and overdosage should not produce any adverse reactions.

4.11 Withdrawal Period(s)

Meat and offal: Zero days. Animals may be slaughtered for human consumption following treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Pyrantel
ATCvet code: QP52AF02

5.1 Pharmacodynamic properties

Pyrantel embonate is a member of the tetrahydropyrimidine class of anthelmintic compounds. It possesses broad spectrum activity against the major gastro-intestinal helminths of animals and man.

It is effective against the following gastro-intestinal helminths of foals and adult horses and donkeys.

Large and small strongyles
(including benzimidazole - resistant strains of small strongyles)
Oxyuris equi
Parascaris equorum
Anoplocephala perfoliata

Pyrantel acts as a potent agonist at acetylcholine (ACh) receptors on muscle cells of nematodes leading to neuromuscular block characteristic of depolarising agents. This results in a prolonged spastic paralysis of the worm and expulsion from the host.

Pyrantel embonate is relatively insoluble and poorly absorbed from the gut. Its activity is confined to parasites dwelling within the gut lumen. The small amount of pyrantel absorbed into the circulation is rapidly metabolised and the drug metabolites have no toxic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Synperonic
Sucrose

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 2 months
Medicated feed or suspension should be used immediately after mixing and any remaining should be disposed of at the end of the day.

6.4 Special precautions for storage

Protect from direct sunlight.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

The product is packed into sachets each containing 7.43 g Strongid P-Granules (5.7 g pyrantel embonate). 15 sachets are included in a carton (sachet pack).

An alternative dispensing pack consists of a drum containing 1.5 kg Strongid P-Granules (1.15 kg pyrantel embonate). Measures and 150 envelopes are included with this pack for veterinary dispensing purposes.
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

Pfizer Healthcare Ireland,
Trading as Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/010/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT