**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

STRONGID™-P Granules 76.736% w/w

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

76.736% w/w of pyrantel embonate.

For the full list of all other excipients see section 6.1

**3. PHARMACEUTICAL FORM**

Granules.

**4. CLINICAL PARTICULARS**

**4.1 Target species**

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

**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**

Not for use in horses with known hypersensitivity to the active ingredient.

* 1. **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 ineddective 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 (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**

i. Special precautions for use in animalsStomach-tube administration: normal precautions should be observed.

Only to be carried out by a veterinary surgeon.

ii. 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.

Avoid inhalation of the product.

Where a number of horses are to be dosed, for example in a yard, it is recommended to wear a dust mask.

**4.6 Adverse reactions (frequency and seriousness)**

None known.

* 1. **Use during pregnancy, lactation or lay**

The product is specifically recommended for use in mares which may be pregnant and/or lactating.

No adverse effects have been found or reported in trials using higher than recommended dosages.

**4.8 Interaction with other medicinal products and other forms of interaction**

None.

**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.

Administer medicated feed or suspension immediately after mixing.

Feed: granules should be dispersed evenly in the feed - preferably a reduced quantity to ensure consumption. Any unconsumed medicated feed should be discarded.

Stomach Tube: Strongid-P Granules suspend in warm water and 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. Any medicated water which is not administered within 24 hours should be discarded.

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).

**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 (300lb) 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, or if this is not possible, delay turning them out until late June.

*Anoplocephala perfoliata* (tapeworm):

The need for retreatment may vary but if considered necessary should be carried out after an interval of six weeks.

* 1. **Overdose (symptoms, emergency procedures, antidotes), if necessary**

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

* 1. **Withdrawal period(s)**

Horse meat: Zero days.

**5. PHARMACOLOGICAL 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, 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 against 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**

Pluronic L121

Sucrose Powder

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Sachet: Part-used sachets should be stored below 25°C and used within 2 months.

**6.4. Special precautions for storage**

If only part of a sachet of granules has been used, fold the opened edge and store in a cool dry place.

Any part used sachets should be stored below 25°C and used within 2 months.

Protect from direct sunlight.

Do not store above 25°C.

* 1. **Nature and composition of immediate packaging**

The product is packed into sachets (paper/aluminium foil/polyethylene) each containing 7.43g Strongid-P Granules (5.7g pytrantel embonate). 15 sachets are included in a carton (sachet pack).

**6.6** **Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Elanco Animal Health

Eli Lilly & Company Limited

Lilly House

Priestly Road

Basingstoke

Hampshire

RG24 9NL

**8. MARKETING AUTHORISATION NUMBER**

**Vm** 00006/4129

**9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

23rd May 2004

**10. DATE OF REVISION OF THE TEXT**

March 2011