SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strongid-P Paste 43.90% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active
Pyrantel Embonate 43.90 %w/w

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral paste.
A smooth, pale yellow to buff paste for oral administration.

4. CLINICAL PARTICULARS

4.1 Target Species

Horses, ponies, donkeys 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.

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.(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 anthelmintics 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 (also widespread in the US and Canada). Therefore the use of this product should be based on a 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 animals

The same oral doser should only be used to dose two animals if they are both healthy and are either running together, or are on the same premises and in direct contact with each other.
Only for direct oral administration.

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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 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 known.

4.9 Amounts to be administered and administration route

Administration:
Strongid-P Paste is recommended for direct oral administration in horses, ponies, donkeys and foals over four weeks of age. It is not necessary to withhold any feed prior to administration. The following method of administration is recommended:

1. Position the locking ring over the appropriate mark on the plunger.
2. Remove the cap from the nozzle.

3. The paste is best deposited on the upper surface of the tongue. Introduce the nozzle end of the oral doser at the corner of the mouth. Direct the oral doser backwards and depress the plunger to deposit the paste onto tongue. Providing the paste is given in this way it is unlikely that any rejection will occur. Raising the head by a hand under the chin sometimes helps with swallowing.

Dosage:
For the control and treatment of strongyles *Oxyuris* and *Parascaris* but excluding *Anoplocephala* (tapeworm). Strongid-P Paste should be used at a dose rate of 19 mg pyrantel embonate per kg bodyweight.

Bodyweight range	Dose – contents of	Dose of pyrantel embonate
Up to 150kg	¼ oral doser	2.85g
151 – 300kg	½ oral doser	5.70g
301 – 450kg	¾ oral doser	8.55g
451 – 600kg	Full oral doser	11.40g

Note: Position locking ring over appropriate mark on plunger.

Dosing Programmes:
Strongyles. *Oxyuris* 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 horses and donkeys are at grass, dose every four to six weeks. Always dose three to four days before turning out after in-wintering.

Suckler mares: It has been shown that reduction of strongyle challenge to the suckling foal at pasture can be achieved by using clean pasture (re-seeded, or not grazed the previously year by horses), 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 June.

Dosage: For the control and treatment of tapeworms: Strongid-P Paste should be used at a dose rate of 38 mg pyrantel embonate per kg bodyweight, that is twice the dose rate for strongyles.

Dosing programme – Tapeworm: The need for re-treatment may vary, but if considered necessary should be carried out after an interval of six weeks.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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)

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 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

Polysorbate 80
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Sorbitol Solution 70%w/w (non-crystallising)
Sodium Alginate
Water purified

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.

6.4 Special Precautions for Storage

Protect from direct sunlight.
Do not store above 25°C.
Store in a tightly closed original container.

6.5 Nature and composition of immediate packaging

Pack size: 26g
Container: Metering syringe with high density polyethylene barrel, plunger and locking ring.
Closure: Low density polyethylene piston and endcap.
Content: Pale yellow to buff coloured oral paste.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

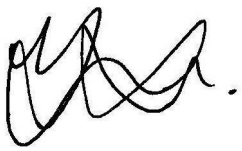
Vm 00879/4176

9. DATE OF THE FIRST AUTHORISATION

23 May 1994

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 01 October 2020