Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Strongid Caramel Oral Paste 43.72 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Pyrantel embonate	43.720 % w/w
Excipients	
Methyl para hydroxybenzoate	0.105 % w/w
Propyl para hydroxybenzoate	0.016 % w/w
Caramel currant flavour	0.050 % w/w

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

Oral paste.

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.*

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

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
The same syringe 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.

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 Caramel is recommended for direct oral administration in horses, ponies and 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 syringe at the corner of the mouth. Direct the oral doser backwards and depress the plunger to deposit the paste onto tongue. Provided the paste is given in this way it is unlikely that any rejection will occur. Raising the horse's head by a hand under the chin sometimes helps with swallowing.

Dosage excluding tapeworms

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

Bodyweight range	Dose - contents of
Up to 150 kg	¼ oral doser
151-300 kg	½ oral doser
301-450 kg	¾ oral doser
451-600 kg	Full oral doser

Note: Position locking ring over appropriate mark on plunger.

Dosing Programmes - excluding tapeworms

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 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 previous 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.

Dosage: - Tapeworms
For the control and treatment of tapeworms Strongid Caramel 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 - Tapewoms:
The need for retreatment may vary, but if considered necessary 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, tetrahydropyrimidines
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 gastrointestinal helminths of animals and man.

In this application for its use in horses it has been shown to be highly effective against the following gastrointestinal helminths of foals and adult horses:

Strongyles (including benzimidazole - resistant strains)
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.

5.2 Pharmacokinetic properties

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 (Tween 80)
Methyl para hydroxybenzoate
Propyl para hydroxybenzoate
Sorbitol Syrup 70%
Sodium alginate
Caramel currant flavour
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 direct sunlight.

6.5 Nature and composition of immediate packaging

Pack size 26 g. Metering syringe with HDPE barrel, plunger and locking ring. LDPE piston and end cap. Ten syringes per carton.

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

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/093/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 25th July 2009

10 DATE OF REVISION OF THE TEXT

December 2014