

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Provid 44 % Oral Paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Pyrantel Embonate 44% w/w
(equivalent to 15.19% w/w Pyrantel base)

Each oral doser contains 11.41 g pyrantel embonate (3.95 g pyrantel base) in 26 g paste.

Excipients

Methyl Parahydroxybenzoate (E218)	0.098% w/w
Propyl Parahydroxybenzoate (E216)	0.044% w/w
Apple Flavouring	

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral paste.

A smooth shiny yellow paste with a characteristic odour of apple.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

Infestations with adult stages of roundworms, large and small strongyles, and seatworm/pinworm in horses over 8 weeks of age.

Infestations of tapeworms in horses, except pregnant mares.

The spectrum of activity includes adult stages of:

Large roundworm:

Parascaris equorum

Large redworms (large strongyles):

Strongylus vulgaris

Strongylus edentatus

Strongylus equinus

**Small redworms (small strongyles)
including benzimidazole resistant strains**

Cyathostomum spp.

Triodontophorus spp.

Seatworm/pinworm:

Oxyuris equi

Tapeworm:

Anoplocephala perfoliata

The efficacy towards *Anoplocephala perfoliata* is variable.

See also Section 4.4

4.3 Contraindications

Do not administer to foals under 8 weeks of age. Treatment against tapeworms is contraindicated in pregnant mares. Do not use in animals known to be hypersensitive to the active substance.

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 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 small strongyles in horses. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of the small strongyles and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

Assess bodyweight as accurately as possible before dosing to avoid underdosing. 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.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Avoid contact with the skin. Wash hands and any other parts of the body, which come in contact with the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant mares for treatment of tapeworms. The product can be safely used during pregnancy and lactation at a dose rate of 19 mg/kg.

4.8 Interaction with other medicinal products and other forms of interaction

The product should not be used concurrently with preparations containing levamisole, piperazine or cholinesterase inhibitors (e.g. organophosphates).

4.9 Amounts to be administered and administration route

For single use only.

The product should be used at a dose-rate of 19 mg/kg pyrantel embonate for the treatment of large and small strongyles (including benzimidazole resistant strains), large roundworms and seatworms/pinworms, i.e. for a horse of 600 kg bodyweight 1 full oral doser will be required.

Bodyweight	Dose
Up to 150 kg	¼ oral doser (150 kg mark)
151 to 300 kg	½ oral doser (300 kg mark)
301 to 450 kg	¾ oral doser (450 kg mark)
451 to 600 kg	1 full oral doser (600 kg mark)
601 to 700 kg	1 ¼ oral doser

For the treatment of tapeworm *Anoplocephala perfoliata*, the product should be used at double this dose-rate (i.e. 38 mg/kg pyrantel embonate), e.g. for a horse of 600 kg bodyweight 2 full oral dosers will be required.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order

to avoid under- or overdosing.

Dosing Programme:

The <?xml:namespace prefix = st1 ns = "urn:schemas-microsoft-com:office:smarttags" /><st1:PersonName w:st="on">vet</st1:PersonName>erinarian should provide advice on a suitable dosing programme. Dosing programme should be adjusted according to national or regional recommendations based on the local epidemiological conditions. The egg reappearance period (ERP) should be taken into consideration. Tapeworm treatment (double dose rate) should only be performed when tapeworms have been diagnosed.

Method of Administration:

For oral administration only.

Position the locking ring over the appropriate mark on the plunger. Administer the paste by depositing on the upper surface of the back of the tongue. Raising the horses head can sometimes assist the swallowing process. Replace the cap on any part used syringes.

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

The product is well tolerated up to 6 times the recommended therapeutic dose for nematodes (114 mg/kg bw). In case of signs of overdosage atropine can be used as antidote.

4.11 Withdrawal Period(s)

Meat and offal: Zero Days.

Not permitted for use in mares producing milk for human consumption

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pyrantel Embonate belongs to the tetrahydropyrimidine class of anthelmintics.
ATCVet Code: QP52AF02

5.1 Pharmacodynamic properties

Pyrantel embonate acts as a cholinergic agonist that leads to a depolarising neuromuscular blockade with spastic paralysis and peristaltic expulsion of the nematode parasites.

Investigations on *Toxocara canis* have shown that pyrantel also affects the energy balance of the parasites by complete disintegration of the mitochondrions of the large muscle cells.

In horses pyrantel embonate is effective against adult stages of ascarids, large and small strongyles, pinworms and *Anoplocephala perfoliata*.

5.2 Pharmacokinetic properties

Pyrantel embonate is an insoluble salt and is not well absorbed from the intestinal tract. It is quickly and almost completely broken down into a number of anthelmintically inactive metabolites. Following administration of the product, the Tmax for pyrantel embonate (including main metabolites) is approximately 6 hours and the

C_{\max} is approximately 350 ng/ml.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol,
Glycerol 86.7 %,
Methyl Parahydroxybenzoate (E218),
Propoyl Parahydroxybenzoate (E216),
Apple flavouring.
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product: 3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Pack size 26 g. Syringes composed of a HDPE barrel and plunger with a LDPE cap and plastic seal and polypropylene multidose ring.
Each syringe is packed into a carton.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/057/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th August 2008

10 DATE OF REVISION OF THE TEXT