Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nematel-P 439 mg/g oral paste for horses.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per gram	
Active substance:	
Pyrantel embonate (equivalent to 152.2 mg of pyrantel)	439 mg
Excipient(s):	
Methyl parahydroxybenzoate (E218)	1 mg
Propyl parahydroxybenzoate (E216).	0.3 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste
Yellow, viscous, oily paste

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, ponies and foals (of over 8 weeks of age).

4.2 Indications for use, specifying the target species

Infestations with adult stages of roundworm, particularly ascarids (*Parascaris equorum*), small strongyles (*Cyathostomum spp., Triodontophorus spp*.) and large strongyles (*Strongylus edentatus, Strongylus equinus, Strongylus vulgaris*), seatworm/pinworm (*Oxyuris equi*) and tapeworm (*Anoplocephala perfoliata*) in horses, ponies and foals.
The efficacy towards Anoplocaphala perfoliata is variable.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

4.4 Special warnings for each target species

Treatment against tapeworms should only be undertaken when tapeworms have been diagnosed.
Resistance to pyrantel embonate has been reported in cyathostomins in horses. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of cyathostomins and recommendations on how to limit further selection for resistance to anthelmintics.

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.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Occurrence of sensitisation and contact dermatitis cannot be completely excluded, so direct contact with the skin should be avoided.
Wear suitable gloves.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Use during pregnancy and lactation is permitted.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Posology

For single oral administration to horses.

(a) For treatment of large and small strongyles, large roundworms and seatworm/pinworms the recommended dose is 19 mg pyrantel embonate per kg of bodyweight. One syringe is intended for 700 or 1200 kg bodyweight (see markings on the applicator) and each syringe is subdivided in markings. The equivalent of one marking is sufficient to treat 50 kg of bodyweight.

(b) For treatment of tapeworms the recommended dose is 38 mg pyrantel embonate per kg of bodyweight. One syringe is intended for 350 or 600 kg bodyweight (see markings on the applicator) and each syringe is subdivided in markings. The equivalent of two markings is sufficient to treat 50 kg of bodyweight.

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

Position the locking-ring over the appropriate mark on the plunger of the syringe and remove the cap from the nozzle, open the mouth of the horse, deposit the paste as far as possible on the back of the tongue and make the horse swallow. The amount of paste requested can be set and locked using the screw-ring nut on the injector. Swallowing can be stimulated by putting a hand under the chin and raising the head of the horse.

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

Nematel-P is well tolerated up to 5 times the recommended therapeutic dose for treatment of nematodes. If overdosing causes signs such as salivation, muscle fibrillations, tachypnoea, dyspnoea, ataxia, tremors or convulsions atropine can be used as an 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

Pharmacotherapeutic group: anthelmintics, tetrahydropyrimidines.
ATCvet code: QP52AF02.

5.1 Pharmacodynamic properties

Pyrantel embonate, the pamoic acid salt of 1,4,5,6-tetrahydro-1-methyl-2-[(trans-2-2-thienyl)-vinyl]-pyrimidine, is an anthelmintic belonging to the tetrahydropyrimidine group.
Pyrantel embonate acts as a cholinergic agonist that leads to a depolarizing neuromuscular blocking with spastic paralysis of the nematode and subsequent removal from the host by peristaltic expulsion. In horses pyrantel embonate is effective towards adult stages of large and small strongyles, the ascarid (*Parascaris equorum*) and the seatworm/pinworm (*Oxyuris equi*). The efficacy towards adult stages of the tapeworm *Anoplocephala perfoliata* is variable.
Less pyrantel-susceptible mutants have been described with partial cross-resistance against morantel and levamisole. Resistance to pyrantel has been reported in small and large strongyles.

5.2 Pharmacokinetic properties

Pyrantel embonate is an insoluble salt and it is not well absorbed from the gastro-intestinal tract. The absorbed fraction is quickly and almost completely broken down in the liver into a number of anthelmintic inactive metabolites.
Excretion of the unabsorbed fraction of pyrantel (embonate) mainly occurs via the faeces. After administration of Nematel-P at a dose of 19 mg pyrantel embonate per kg bodyweight a maximum pyrantel concentration of 733 mg/kg faeces is detected within 24 hours; three days after administration no pyrantel could be detected in the faeces anymore. After administration of Nematel-P at 38 mg pyrantel embonate/ kg bodyweight, pyrantel was still detected in the faeces after 3 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Polysorbate 80 (E433)
Colloidal anhydrous silica (E551)
Maize oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 1 month.

6.4 Special precautions for storage

Do not store above 25 °C.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

Pre-filled multi-dose polyethylene syringe with adjustable screw ring closed with a polyethylene cap.
Each syringe contains 30.33 or 52 g paste.

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

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10475/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th February 2009

10 DATE OF REVISION OF THE TEXT

September 2013