1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Embotape 400 mg/g Oral Paste for Horses and Ponies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

Active substance:	**Per 28.5 g Syringe**	**Per 57 g Syringe**
Pyrantel embonate	11.4 g	22.8 g

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**	
Butylated Hydroxytoluene (E321)	Per 28.5 g Syringe	Per 57 g Syringe
	0.0057 g	0.0114 g
Polysorbate 80		
Colloidal Anhydrous Silica		
Maize oil		

A pale coloured to buff coloured paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies.

3.2 Indications for use for each target species

For the control and treatment of adult infections of large and small *Strongyles, Oxyuris, Parascaris* and *Anoplocephala perfoliata*.

3.3 Contraindications

Do not use in severely debilitated animals.

3.4 Special warnings

Only intended for direct oral administration.
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.
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.

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 under-estimation of the bodyweight, misadministration of the veterinary medicinal product or lack of calibration of the dosing device (if any).

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with the skin. Wash hands and any other parts of the body which come into contact with the veterinary medicinal product after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses and ponies:

Undetermined frequency (cannot be estimated from the available data)	Increased skin sensitivity

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system.
See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used on pregnant and lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

Combined administration of pyrantel and levamisole or piperazine is not recommended.

3.9 Administration routes and dosage

For oral use only.

Control and treatment of *Strongyles*, *Oxyuris* and *Parascaris:*

This veterinary medicinal product should be used at a dose rate of 19 mg pyrantel embonate per kg body weight. Suggested dosing programmes are as follows:

a) Foals (1 - 8 months of age): dose every 4 weeks.

b) Horses (over 8 months of age): dose every 6 - 8 weeks, but during the summer and autumn when at grass dose every 4 - 6 weeks. Always dose 3 - 4 days before turning out after in-wintering.

c) 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 3 - 4 days before turning out and then at intervals of 2 - 4 weeks until the end of Autumn. Ideally mares with foals should go out to “clean” pasture.

28.5 g Syringe:
The appropriate amount of the product is deposited on the tongue of the animal and the animal allowed to swallow. The complete content of one syringe contains 11.4 g pyrantel embonate (6

graduated doses of 1.9 g) in 28.5 g paste and is sufficient for the treatment of 600 kg bodyweight. Each graduation of the syringe is sufficient for the treatment of 100 kg bodyweight.

57 g Syringe:
The appropriate amount of the product is deposited on the tongue of the animal and the animal allowed to swallow. The complete content of one syringe contains 22.8 g pyrantel embonate (12 graduated doses of 1.9 g marked in 100 kg intervals from 0 to 1200 kg) in a 57 g paste and one syringe is sufficient for the treatment of 1200 kg bodyweight. Each graduation of the syringe is sufficient for the treatment of 100 kg bodyweight.

Control and treatment of *Anoplocephala* (Tapeworms):

28.5 g Syringe:
This veterinary medicinal product should be used at a dose rate of 38 mg pyrantel embonate per kg bodyweight (i.e. twice the dose used for strongyles). Two syringes are sufficient for the treatment of 600 kg bodyweight. The need for re-treatment may vary, but if considered necessary, should be carried out after an interval of 6 weeks.

57 g Syringe:
This veterinary medicinal product should be used at a dose rate of 38 mg pyrantel embonate per kg bodyweight (i.e. twice the dose used for strongyles). One syringe is sufficient for the treatment of 600 kg bodyweight. The need for re-treatment may vary, but if considered necessary, should be carried out after an interval of 6 weeks.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Pyrantel embonate is of low acute oral toxicity. Oral doses of up to 2000 mg/kg bodyweight in mice and rats and 1000 mg/kg in dogs have produced no evidence of toxicity.

Pyrantel embonate, at dosages of up to 60 mg/kg bodyweight, as base, (some 20 times the standard therapeutic dose) had no adverse effects on horses, ponies or foals. Monitoring included haematological parameters, serum cholinesterase and glutamic oxaloacetic transaminase levels.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 7 days.
Milk: Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AF02.

4.2 Pharmacodynamics

Pyrantel embonate is a broad spectrum anthelmintic with a depolarising neuromuscular blocking action which results in spastic paralysis of the worm, and their expulsion from the intestinal tract.

Pyrantel embonate also inhibits cholinesterases which contributes to its neuromuscular effects.

Pyrantel embonate has a broad spectrum of activity, including activity against:

Large strongyles:	*Strongylus vulgaris, S. edentatus, S. equinus.*
Small strongyles:	*Trichonema* spp.(*Cyathostomes*), *Triodontophorus* spp.
Pinworms:	*Oxyuris equi, Probstmayria vivipara.*
Large roundworms:	*Parascaris equorum.*
Tape worms:	*Anoplocephala perfoliata.*

4.3 Pharmacokinetics

Pyrantel embonate is poorly absorbed from the gastrointestinal tract, making it suitable for use as an intestinal anthelmintic. The small amount of pyrantel embonate which is absorbed is quickly metabolised with little being excreted intact.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
57 g Syringe: This is a single dose veterinary medicinal product. Discard after use.

5.3 Special precautions for storage

Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

White, high density polyethylene syringe with a low density polyethylene cap. The syringe is fitted with a screw ring on a graduated plunger allowing adjustment of 1 to 6 doses (28.5 g syringe) or 1 to 12 doses (57 g syringe) of the veterinary medicinal product.

Pack sizes:
28.5 g Syringe: Each box contains 20 × 28.5 g syringes.
57 g Syringe: Each box contains 20 × 57 g syringes.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/015/001

8. DATE OF FIRST AUTHORISATION

09 January 1998

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12 March 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).