

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10960/025/001**

Case No: 7006835

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Cross Vetpharm Group Ltd.

Broomhill Road, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Embotape Oral Paste 400 mg/g

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **19/03/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Embotape Oral Paste 400 mg/g

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
<u>Excipients</u>		
Butylated Hydroxytoluene (E321)	0.0057 g	0.0114 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste. A pale coloured to buff coloured paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and ponies.

4.2 Indications for use, specifying the target species

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 severely debilitated animals.

4.4 Special warnings for each target species

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, mis-administration of the product or lack of calibration of the dosing device (if any).

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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 product after use.

4.6 Adverse reactions (frequency and seriousness)

Occasional skin sensitisation may occur.

4.7 Use during pregnancy, lactation or lay

The product may be used on pregnant and lactating mares.

4.8 Interaction with other medicinal products and other forms of interaction

Combined administration of pyrantel and levamisole or piperazine is not recommended

4.9 Amounts to be administered and administration route

For direct oral administration only.

Control and treatment of Strongyles, Oxyuris and Parascaris:

Embotape should be used at a dose rate of 19 mg pyrantel embonate per kg bodyweight. 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 11.4g pyrantel embonate (6 graduated doses of 1.9g) in 28.5g 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.

57.0 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 22.8g pyrantel embonate (12 graduated doses of 1.9g marked in 100 kg intervals from 0 to 1200 kg) in a 57g 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 (tapeworm):

28.5 g Syringe

Embotape 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.

57.0 g Syringe

Embotape 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.

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

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.

4.11 Withdrawal Period(s)

Horses may be slaughtered for human consumption only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP52AF02

Pharmacotherapeutic Group: Anthelmintics, Pyrantel

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 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.

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*

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxytoluene (E321)

Polysorbate 80

Colloidal Anhydrous Silica

Maize Oil Refined

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

This is a single dose product. Discard after use.

6.4 Special precautions for storage

Protect from direct sunlight.

6.5 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 syringe) or 1 to 12 doses (57 g syringe) of the product.

28.5g syringe: Each box contains 20 × 28.5 g syringes

57g syringe: Each box contains 20 × 57g syringes

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

Cross Vetpharm Group Limited
Broomhill Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/025/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th January 2008

10 DATE OF REVISION OF THE TEXT

19th March 2010