PRODUCT INFORMATION

EMBOTAPE

Each 28.5g syringe contains 11.4g pyrantel embonate/syringe

INDICATIONS

Pyrantel Embonate is a broad spectrum anthelmintic. Pyrantel embonate is indicated for use in the horse for the control and treatment of adult infections of large and small stronglyles, pinworms, roundworms and tapeworms.

BENEFITS

- For the treatment and control of adult infestations of large and small redworms ascarids and pinworms
- For the treatment and control of tapeworm
- Calibrated syringe for accurate dosage
- Broad spectrum activity of pyrantel embonate

PACKAGING

LIST NO.	UNIT PACKAGE	CASE SIZE
1EMB004	28.5G SYRINGE	20

See reverse side for Administration and Dosage.

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EMBOTAPE

Pyrantel embonate 11.4g/syringe

TARGET SPECIES
Horses and ponies.

INDICATIONS FOR USE, SPECIFYING THE TARGET SPECIES
Pyrantel embonate is a broad spectrum anthelmintic. Pyrantel embonate is indicated for use in the horse for the control and treatment of adult infections of large and small strongyles, Pinworms, Roundworms, Tapeworms.

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

Large strongyles:	*Stronglylus 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.*

CONTRAINDICATIONS
Not for use in foals less than 4 weeks of age.
Contraindicated in known sensitivity to pyrantel and in severely debilitated animals.

SPECIAL WARNINGS FOR EACH TARGET SPECIES
Care should be taken to avoid the following practices because they increase the risk of development of resistence 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 weight, misadministeration of the product, or lack of calibration of the dosing device(if any).

Suspected clinical cases of resistence 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 (also widespread in the USA and Canada). 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 resistence to anthelmintics.

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.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS
Direct contact with the skin should be avoided.
Wash hands and any other parts of the body which comes into contact with the product after use.
Avoid handling the product if you know you are hypersensitive to pyrantel.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)
Pyrantel embonate is safe for horses and ponies of all ages, including sucklings, pregnant mares and studs. Impaction of the small intestine may occur in foals, infected with high numbers of Parascaris equorum. Symptoms (colic) may be seen as soon as 30 minutes after treatment.

USE DURING PREGNANCY, LACTATION OR LAY
Embotape is safe to give to pregnant and lactating mares provided the recommendations are followed.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS
Combined administration of pyrantel and levamisole or piperazine is not recommended.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE CONTROL AND TREATMENT OF STRONGYLES, OXYURIS AND PARASCARIS:
Embotape should be used at a dose rate of 19 mg pyrantel embonate per kg bodyweight. The 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 or, if this is not possible, delay turning them out until June.
The prescribed amount of Embotape 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 600kg bodyweight. Each graduation of the syringe is sufficient for the treatment of 100kg body-weight.

CONTROL AND TREATMENT OF ANOPLOCEPHALA (TAPEWORM):
Embotape should be used at a dose rate of 38mg pyrantel embonate per kg bodyweight (i.e. twice the dose used for strongleyes). The need for re-treatment may vary, but if considered necessary, should be carried out after an interval of 6 weeks.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY.
Pyrantel embonate is of low accurate oral toxicity. Oral doses of up to 2000mg/kg bodyweight in mice and rats and 1000mg/kg in dogs have produced no evidence of toxicity.

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

WITHDRAWAL PERIODS
Not to be used in horses and ponies intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

INCOMPATIBILITIES (MAJOR)
None Known

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

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C.
Protect from direct sunlight.

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING
28.5g white, low 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 of the product. Graduations on the syringe at 100kg bodyweight intervals.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS, IF APPROPRIATE
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
Cross Vetpharm Group Ltd. Broomhill Road, Tallaght,
Dublin 24. Ireland

MARKETING AUTHORISATION NUMBER
VPA 10960/025/001

LEGAL CATEGORY:
POM-VPS

PACKAGE QUANTITIES:
Single Syringe

A full product SPC is available on request from Bimeda or alternatively can be found on the VMD website