Consumer leaflet for a Veterinary Product
This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. NAME OF THE VETERINARY MEDICINE, FORM AND STRENGTH

Embotape Veterinary
Paste, Per OS

2. ACTIVE INGREDIENT and its quantity in a unit dose

Pyrantel embonate 11.4 gr / dose
Each syringe of 28.5 gr contains 11.4 gr Pyrantel embonate.

In addition, it contains 0.0057 gr Butylated hydroxytoluene
For the full list of inactive excipients and allergens included in this product - see Section 13 of this leaflet: " Additional information."

3. WHAT IS THE MEDICINE INTENDED FOR

Embotape Veterinary is indicated for the control and treatment of adult infections in horses of large and small Strongyles, Oxyuris, Parascaris and Anoplocephala perfoliata.

Therapeutic group: for the treatment of worms in animals (anthelmintic)

4. CONTRAINDICATIONS

Do not use the product in foals less than 4 weeks of age.
Do not use the product if there is known sensitivity to the active substance Pyrantel embonate
Do not use the product in severely debilitated animals.

5. SIDE EFFECTS

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- episodes of spasmodic abdominal pain) may be seen as soon as 30 minutes after treatment.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il

6. TARGET SPECIES

Horses

7. DOSAGE AND ADMINISTRATION ROUTE

Treatment planning:
During the grazing season, horses over 8 months of age should receive treatment with Embotape every 4-6 weeks. During the rest of the year, horses should be treated every 6-8 weeks. New horses and horses that have been kept indoors during the winter should be treated and left indoors for 3-4 days.
A veterinarian should be consulted on the recommended dosage for the treatment and prevention of worms, in order to prevent the development of resistance to the worm medicine.
It is recommended that mares with foals graze in an area where no other horses have grazed in the previous 12 months. When this is not possible, it is recommended that they graze in an area where no other horses have grazed in the period between January and May. This will reduce the chance of the foal getting infected with worms.
The mare should be treated 3-4 days before being put out to pasture and then at intervals of 2-4 weeks until the end of autumn. Foals aged 1-8 months should be treated every 4 weeks. Do not treat at an age less than 4 weeks.

Dosage and instructions for use:
One syringe contains a dose sufficient for 600 kg of body weight. Each marking on the syringe gives a dose sufficient for 100 kg of body weight.
In the treatment of Tapeworm (Anoplocephala), the dose must be doubled, i.e., 2 syringes are required to treat 600 kg of body weight (2 markings on the syringe to treat 100 kg of body weight).
Body weight should be estimated as accurately as possible before the treatment.
The product should be applied to the back of the horse's tongue. Lifting the head will help the horse to swallow the product.

Dosage recommendations:

The weight of the horse	type / breed	Dose for routine treatment
Up to 100 kg	A miniature pony	up to the 100 mark on the syringe
101-300 kg	Foals, ponies, donkeys	up to the 300 mark on the syringe

301-400 kg	Medium horses	up to the 400 mark on the syringe
401-500 kg	Arabian horses	up to the 500 mark on the syringe
501-600 kg	big horses	up to the 600 mark on the syringe
601 kg and above	Horses of a very large breed	1 syringe + additional 100 on the syringe per 100 kg of body weight.

8. HOW TO USE THE PRODUCT

The prescribed dosage should be administered on the animal tongue and the animal allowed to swallow.

9. WITHDRAWAL PERIOD

Not applicable

10. WARNINGS

- Special warnings for safe use of the medicine in target 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 the active ingredient Pyrantel embonate.

- Additional warnings

During the treatment, the following actions should be avoided 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 the horse weight, misadministration of the product, or lack of calibration of the dosing device.

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 tests 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, therefore the use of this product should be based on local epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

- Pregnancy or lactation of the treated animal

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 embonate and levamisole or piperazine is not recommended.

- Overdose

Pyrantel embonate is of low accurate oral toxicity. Oral doses of up to 2000 mg/kg body weight 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 body weight, 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.

- Incompatibility

Not known

11. STORAGE INSTRUCTIONS

- Avoid poisoning! Keep this medicine and any other medicine in a closed place out of reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date (exp. Date) shown on the package. The expiry date refers to the last day of the month indicated.
- Store below 25^0C. Protect from direct sunlight.
- The syringe is for single use only. Do not keep the syringe for reuse.

12. INSTRUCTIONS FOR DISPOSING OF THE PRODUCT / REMAINING PRODUCT AT THE END OF ITS USE

Any unused veterinary medicinal product or waste materials derived from veterinary medicinal product use, should be disposed of as toxic waste. Do not throw into the sewage system.

13. ADDITIONAL INFORMATION

- In addition to the active substance, the medicine also contains:

Polysorbate 80, Silica Colloidal Anhydrous, Maize Oil Refined, Butylated Hydroxytoluene (E132).

- Medicine appearance and package contents:

28.5g white, polyethylene syringe with a 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 100 kg body weight intervals.
The paste is pale to buff colored.

- Registration holder: Eliezer Linevitz Ltd. Kanot Industrial area, adom 6 St. P.O.B 7006, Israel.

- The manufacturer: Bimeda Animal Health Limited, 2, 3 & 4 Airton Close, Airton Road, Tallaght, Dublin 24, Ireland

Revised in September 2022 according to MOH guidelines

Registration number of this medicine in the Ministry of Health State Medicine Registry: 083-66-92380