

ANNEX II

Not applicable

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Syringe Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Embotape Horse Wormer
40% w/w Oral Paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 11.4g pyrantel embonate per syringe

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

28.5 gram per syringe

5. TARGET SPECIES

Horses and ponies

6. INDICATION(S)

Not applicable – prescription medicine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For Oral Administration
For uses, dosage, contra-indications and warnings, see syringe carton

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Treated horses may never be slaughtered for human consumption.
The horse must be declared as not intended for human consumption under national passport legislation.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Protect from direct sunlight
Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only.
To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4014

17. MANUFACTURER’S BATCH NUMBER

BN:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

{NATURE/TYPE}

Not applicable

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

Not applicable

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Syringe Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Embotape Horse Wormer
40% w/w Oral Paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Presentation: Embotape is a ready to administer oral paste for horses and other equines. Each 28.5g syringe contains 11.4g pyrantel embonate as active ingredient.

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

28.5 gram

5. TARGET SPECIES

Horses and ponies

6. INDICATION(S)

Uses: For the treatment and control of adult infections of large and small redworms, ascarids and pinworms found in the gastro-intestinal tract of horses and other equines. Embotape also treats and controls tapeworm.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One syringe per 600kg bodyweight as a single dose (which is equivalent to one syringe mark per 100kg 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.

Increased dosing for treatment of Tapeworm infections

Double the routine dose rate and administer on a single occasion, i.e. Two syringes per 600kg bodyweight as a single dose (which is equivalent to two syringe marks per 100kg bodyweight)

Assess as accurately as possible before calculating the dosage. The use of a 'weigh band' is recommended. Administer the paste by squeezing from the syringe onto the back of the horse's tongue.

Practical dosage Recommendations

Weight	Type	Routine Treatment
Up to 100kg	Miniature ponies	Syringe mark 100kg
101 – 300kg	Donkey, Shetland and other small ponies, foals.	Syringe mark 300kg (1/2 syringe)
301 – 400kg	Dartmoor, New Forest, Welsh	Syringe mark 400kg
401 – 500kg	Light hunters, Arabs, etc.	Syringe mark 500kg
501 – 600kg	Thoroughbreds	Syringe mark 600kg (1 syringe)
601kg and over	Heavy hunters, draught horses	1 full syringe plus additional 100kg syringe marks for each extra 100kg bodyweight.

Dosing Programmes

During the grazing season, all horses over 8 months of age should be wormed with Embotape every 4 – 6 weeks. For the remainder of the year, horses should be wormed with Embotape every 6 – 8 weeks.

New horses and horses which have spent the winter inside, should be wormed with Embotape and then kept in for 3 – 4 days before turnout.

Mares and foals

Mares with foals should preferably be grazed on pasture which has not been grazed by other horses for the previous 12 months. Where this is not possible, pasture which has not been grazed by other horses from January to the end of May should be used and turnout delayed until June. This will help to reduce the roundworm challenge to the foal.

Foals aged 1 – 8 months should themselves be treated with Embotape every 4 weeks

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

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.

Do not use in severely debilitated animals.

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

User Safety Warnings

Direct contact with the skin should be avoided; wash hands and any other parts of body which come in contact with the product after use. Avoid handling the product if you know you are hypersensitive to pyrantel.

The same syringe should only be used to dose two animals if they are both healthy and are either grazing together, or are on the same premises and in direct contact with each other.

Embotape is safe for horses and ponies over 1 month of age, including suckling foals, pregnant mares and stallions. Impaction of the small intestine may occur in foals heavily infected with ascarids. Colic symptoms may be seen as soon as 30 minutes after treatment.

10. EXPIRY DATE

EXP Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Protect from direct sunlight.

On occasions where only part of the paste is used, replace the cap and store as indicated.

Keep container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only.

To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4014

17. MANUFACTURER’S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Embotape Horse Wormer
40% w/w Oral Paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 20 syringes each containing 28.5g Embotape oral paste.
Each syringe of paste contains 11.4g pyrantel embonate.

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

20 x 28.5g syringes

5. TARGET SPECIES

Horses and ponies

6. INDICATION(S)

Not applicable – prescription medicine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Practical dosage Recommendations

Weight	Type	Routine Treatment
Up to 100kg	Miniature ponies	Syringe mark 100kg
101 – 300kg	Donkey, Shetland and other small ponies, foals.	Syringe mark 300kg (1/2 syringe)
301 – 400kg	Dartmoor, New Forest, Welsh	Syringe mark 400kg

401 – 500kg	Light hunters, Arabs, etc.	Syringe mark 500kg
501 – 600kg	Thoroughbreds	Syringe mark 600kg (1 syringe)
601kg and over	Heavy hunters, draught horses	1 full syringe plus additional 100kg syringe marks for each extra 100kg bodyweight.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Protect from direct sunlight.
Keep container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of used syringes in the farm refuse. Used syringes should not be recycled.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only.
To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Vm 50146/4014

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Embotape Horse Wormer:

Not applicable as all required information is on the product containers

Approved: 25 October 2018

D. Austin