

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Syringe Label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Pyratape P 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

**5. TARGET SPECIES**

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**

Not to be used in horses and ponies intended for human consumption  
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 the outer carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**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 sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

Distributed by:  
MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER**

Vm 50146/4013

**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**  
**Cardboard box of 1 x 28.5 g syringe**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Pyratape P Horse Wormer  
40% w/w Oral Paste

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Pyratape P 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)**

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. Pyratape P 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)

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)

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. 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.

### **8. WITHDRAWAL PERIOD**

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.

### **9. SPECIAL WARNING(S), IF NECESSARY**

#### CONTRA-INDICATIONS AND WARNINGS

Do not use in severely debilitated animals

#### OPERATOR WARNINGS

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

### **10. EXPIRY DATE**

EXP:



**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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**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 sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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Tallaght  
Dublin 24  
Ireland

Distributed by:  
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BN:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer Carton**  
**Cardboard box of 20 x 28.5 g syringes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Pyratape P Horse Wormer  
40% w/w Oral Paste

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains 20 syringes each containing 28.5g Pyratape P 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 each extra bodyweight.	Heavy hunters, draught horses	1 full syringe plus additional 100kg syringe marks for 100kg

## **8. WITHDRAWAL PERIOD**

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.

## **9. SPECIAL WARNING(S), IF NECESSARY**

See syringe carton for user warnings.

## **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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **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”**

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BN:

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**

Pyratape P Horse Wormer:

Not applicable as all required information is on the product containers

A handwritten signature in black ink, appearing to be 'H. M. ...', located above the approval date.

Approved 27 July 2020