

**LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

Nobilis Paramyxo P201

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)**

Per dose:  
≥ 6.8 to ≤ 10.2 log<sub>2</sub> HI inactivated PPMV-1, strain P201.  
138 mg Liquid paraffin

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

20, 50 or 250 ml

**5. TARGET SPECIES**

Pigeons

**6. INDICATION(S)**

Vaccine against PPMV-1 infections.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous injection.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

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

Accidental self-injection is dangerous – see package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}  
Once broached use immediately.

**11. SPECIAL STORAGE CONDITIONS**

Store at 2 - 8°C. Do not freeze.

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

Disposal: read package leaflet.

**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.

**14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"**

Keep out of the reach and sight of children

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

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/3027

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING**

**250 ml**

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

Nobilis Paramyxo P201

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)**

Per dose:

$\geq 6.8$  to  $\leq 10.2$   $\log_2$  HI inactivated PPMV-1, strain P201.

138 mg Liquid paraffin

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

250 ml

**5. TARGET SPECIES**

Pigeons

**6. INDICATION(S)**

Vaccine against PPMV-1 infections.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous injection.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

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

Accidental self-injection is dangerous – see package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Do not freeze.

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

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

**14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"**

Keep out of the reach and sight of children

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

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/3027

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

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

20, 50 ml

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

Nobilis Paramyxo P201

**2. QUANTITY OF THE ACTIVE SUBSTANCE**

Per dose:  
 $\geq 6.8$  to  $\leq 10.2 \log_2$  HI inac. PPMV-1

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBERS OF DOSES**

20, 50 ml

**4. ROUTE(S) OF ADMINISTRATION**

s.c.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

MSD Animal Health Logo

**PACKAGE LEAFLET**

**PACKAGE LEAFLET**  
**Nobilis Paramyxo P201, Emulsion for injection**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:  
MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer for batch release:  
Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

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

Nobilis Paramyxo P201

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

Pigeon Paramyxo virus-1 (PPMV-1) antigen strain P201, inactivated : inducing  $\geq 6.8 \log_2 \text{HI}^*$  and  $\leq 10.2 \log_2 \text{HI}$  units in chickens

\*Haemagglutination Inhibition

Liquid Paraffin

**4. INDICATION(S)**

Active immunisation of pigeons to reduce clinical signs caused by virulent PPMV-1 infection. The vaccine has been shown to significantly reduce virus excretion after challenge.

Onset of immunity: 4 weeks after primary vaccination.  
A duration of immunity of 1 year has been demonstrated.

**5. CONTRAINDICATIONS**

Do not use in sick animals.

**6. ADVERSE REACTIONS**

No clinical signs have been observed after vaccination.



If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Pigeons

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

0.25 ml per dose

Each animal should be given 0.25 ml of vaccine by subcutaneous injection into the lower back area of the neck.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Birds can be vaccinated from five weeks of age.

Allow the vaccine to reach ambient temperature (15-25°C) before use. Shake well before use. Use sterile syringes and needles.

## **10. WITHDRAWAL PERIOD**

Zero days

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Store in a refrigerator (2 to 8°C). Do not freeze.

Use immediately after opening of the container.

## **12. SPECIAL WARNINGS**

To the user:

This product contains mineral oil. Accidental injection/self injection could result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with the product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product may cause intensive swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of a finger pulp or tendon.

Vaccination within 4 weeks of the start of the breeding season is not recommended. No information is available on the safety of this product during the reproduction period.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Two-fold the recommended dose was shown to be safe for the target species. Do not mix with any other vaccine/immunological products.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused product or waste material should be disposed of in accordance with national requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED**

August 2020

**15. OTHER INFORMATION**

PET vials of 20, 50 or 250 ml. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Approved 14 August 2020

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.