

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 log₂ 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 01708/5097

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:

≥ 6.8 to ≤ 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 01708/5097

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:
 ≥ 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 Paramyxovirus-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.