PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201 emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 0.25 ml contains:
Inactivated PPMV-1, strain P201: $\geq$ 6.8 to $\leq$ 10.2 $\log_2$ HI* units in chickens

*HI = haemagglutination inhibition

3. PACKAGE SIZE

20 ml (80 doses)
50 ml (200 doses)
250 ml (1000 doses)

4. TARGET SPECIES

Pigeons

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5031

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
(50 ml, 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201 emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

250 ml (1000 doses)

Each dose of 0.25 ml contains:
Inactivated PPMV-1, strain P201: $\geq$ 6.8 to $\leq$ 10.2 $\log_2$ HI* units in chickens

*HI = haemagglutination inhibition

3. TARGET SPECIES

Pigeons

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.
Store in a refrigerator.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous.

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

Disposal: Read package leaflet

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-VPS Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 ml (80 doses)

Per dose (0.25):
Inac. PPMV-1: ≥ 6.8 to ≤ 10.2 log2 HI

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

5. ROUTE(S) OF ADMINISTRATION

S.C.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201 emulsion for injection for pigeons

2. COMPOSITION

Each dose of 0.25 ml contains:

Active substance:
Inactivated pigeon paramyxo virus-1 (PPMV-1) antigen strain P201: inducing ≥ 6.8 $\log_2$ HI* and ≤ 10.2 $\log_2$ HI units in chickens.

* HI = Haemagglutination Inhibition

Adjuvant:
Liquid paraffin: 138 mg

White to nearly white water-in-oil emulsion.

3. TARGET SPECIES

Pigeons.

4. INDICATIONS FOR USE

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.
Duration of immunity: 1 year after primary vaccination.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal 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 this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet 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 veterinary medicinal 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.

Laying birds:
Do not use in breeding birds and within 4 weeks before the start of the breeding season.
The safety of the veterinary medicinal product has not been established during the reproduction period.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose:
No adverse effects have been observed after the administration of a double dose of the vaccine.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

Pigeons:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For subcutaneous use.

Primary vaccination: One single subcutaneous injection of 1 dose of 0.25 ml per bird from 5 weeks of age into the lower back area of the neck.

Annual revaccination with 1 dose administered according to the primary vaccination schedule is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIODS

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C - 8°C).
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06376/5031

Pack sizes:
Cardboard box with one bottle of 20 ml (80 doses), 50 ml (200 doses) or 250 ml (1000 doses).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

For animal treatment only.

POM-VPS Veterinary medicinal product subject to prescription.

Gavin Hall

Approved: 25 February 2025