SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201 emulsion for injection for pigeons

2. QUALITATIVE AND QUANTITATIVE 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

Excipient:

For a list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White to nearly white water-in-oil emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigeons.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigeons:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amount(s) to be administered and administration route

For subcutaneous use.

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, Pigeon, inactivated bacterial vaccines, pigeon paramyxovirus.

ATC Vet Code: QI01EA01

To stimulate active immunity against PPMV-1 infection in pigeons.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbat 80
Sorbitan mono-oleate
Glycine
Water for injection.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening: immediate use after opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Multidose polyethylene terephthalate (PET)bottle of 20, 50, and 250 ml, closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box with one bottle of 20, 50 or 250 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5031

9. DATE OF FIRST AUTHORISATION

10 October 2002

10. DATE OF REVISION OF THE TEXT

February 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

National and legislation on PMV-1 infections (PPMV-1, Newcastle Disease, etc.) should be considered with regard to the use of this product, as vaccination of certain subclasses of pigeons may be prohibited in some countries.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 25 February 2025