1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Paramyxo P201

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.25 ml:

Active substance:

Pigeon Paramyxo virus-1 (PPMV-1) antigen strain P201, inactivated : inducing ≥ 6.8 log_2 HI* and ≤ 10.2 log_2 HI units in chickens

*Haemagglutination Inhibition

Excipient:
Liquid paraffin 138 mg

For a list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection

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.
A duration of immunity of 1 year has been demonstrated.

4.3 Contraindications

Do not use in sick animals.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

No clinical signs have been observed after vaccination.

4.7 Use during lay

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.

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 Amounts to be administered and administration route

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

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

Birds can be vaccinated from five weeks of age.

Annual revaccination is recommended.

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

Following the administration of a double dose of vaccine no side effects other than those described in section 4.6 have been observed.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against PPMV-1 infection in pigeons.
ATC vet. Code QI 01 EA 01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbat 80, Sorbitan mono-oleate, Glycine, Water for injection.

6.2 Incompatibilities

Do not mix with any other vaccine/immunological products.

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.

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

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

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Korverstraat 35
NL 5831 AN Boxmeer

Represented by the national companies in the Concerned Member States

8. MARKETING AUTHORISATION NUMBER:

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION:

28.03.2000 / 05.04.2005 and 05.04.2010

10. DATE OF REVISION OF THE TEXT

December 2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

National and EU 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.