

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **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  $\geq 6.8 \log_2 \text{HI}^*$  and  $\leq 10.2 \log_2 \text{HI}$  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: QI01EA01

### **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 nitril 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**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

## **8. MARKETING AUTHORISATION NUMBER**

Vm 01708/3027

## **9. DATE OF FIRST AUTHORISATION**

10 October 2002

## **10. DATE OF REVISION OF THE TEXT**

August 2020

## **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.

Approved 14 August 2020

