

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF VETERINARY MEDICINAL PRODUCT**

Nobilis Diluent Oculo Nasal

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Composition per ml

Monobasic potassium phosphate	0.37 mg
Disodium phosphate dihydrate	0.72 mg
Sodium chloride	7.65 mg
Disodium edetate	0.5 mg
Patent Blue V (E131)	0.17 mg
Water for injections	ad 1.0 ml

### **3. PHARMACEUTICAL FORM**

Clear, blue, solution consisting of sterile phosphate buffered saline and EDTA.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Poultry

#### **4.2 Indications for use specifying the target species**

Diluent for reconstitution of Nobilis live vaccines licensed for Oculo/nasal administration to poultry.

#### **4.3 Contra-indications and warnings in respect of other products used in the host immunological status of host and physiological status of host**

Any contra-indications specified for the vaccine for which the diluent is used for reconstitution will apply.

#### **4.4 Specific warnings for each target species**

None

#### **4.5 Special precautions for use**

##### 4.5.1 Special precautions for use in animals

No special precautions are required for handling the diluent however any

recommendations specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as a diluent will apply.

**4.5.2 Special precautions to be taken by the person administering the product to animals**

None

**4.6 Adverse reactions (frequency and seriousness)**

Any adverse effects specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent will apply.

**4.7 Use during pregnancy and lactation**

Any recommendations specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent will apply.

**4.8 Interaction with other medicaments and other forms of interaction**

None known.

**4.9 Amounts to be administered and administration route**

The instructions supplied with the vaccine should be read carefully before using the diluent.

For freeze dried vaccines the contents of the diluent vial should be transferred aseptically into the vial of freeze-dried vaccine immediately prior to use.

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

No specific treatment or antidote recommended

**4.11 Withdrawal periods**

Zero days

**5. PHARMACOLOGICAL PROPERTIES**

Not applicable. The diluent does not contain active ingredients.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

No other ingredients than those listed under 2.

## **6.2 Incompatibilities**

None known

## **6.3 Shelf life and in-use shelf life**

Shelf life of the veterinary medicinal product as packaged for sale  
48 months

Shelf life after dilution or reconstitution according to directions

In-use shelf life is that specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent.

## **6.4 Special precautions for storage**

Do not store above 25°C.

Keep the container in the outer carton

## **6.5 Nature and composition of immediate packaging**

The product is supplied in cartons with 10 PET vials containing 31.5 or 79 ml closed with a halogenated butyl rubber stopper and an aluminium crimp cap. Not all presentations may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such veterinary medicinal 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 01708/4502

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

09 November 2005

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

February 2021

Approved 12 February 2021

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.