

**I. SUMMARY OF PRODUCT CHARACTERISTICS**

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

NOBILIS® INFLUENZA H5N2

Avian Influenza Type A, subtype H5N2, strain A/duck/Potsdam/1402/86. Inactivated Vaccine.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Nobilis Influenza H5N2 is available in vials of 500 ml containing 1000 doses of 0.5 ml.

**Active component**

Avian Influenza Type A, subtype H5N2 inducing a HI titre of  $\geq 6.0 \log_2$  per dose, according to the potency test.

**Adjuvant**

Nobilis Influenza H5N2 is a water-in-oil emulsion vaccine.

**3. PHARMACEUTICAL FORM**

Water-in-oil emulsion for SC or IM injection. Vaccine is ready for administration.

**4. IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against Avian Influenza virus type A, subtype H5. The inactivated antigen is incorporated in a water-in-oil emulsion in order to enhance immunity.

Selecting a vaccine strain that has a different N component to the avian influenza field virus facilitates the possible differentiation between vaccinated and infected poultry using a diagnostic test detecting Neuraminidase antibodies.

**5. CLINICAL PARTICULARS**

**5.0 Target species**

Poultry

**5.1 Indications for use**

Nobilis Influenza H5N2 is meant to be used for active immunization of healthy poultry as an aid in the control of Avian Influenza type A subtype H5.

**5.2 Contraindications**

None

**5.3 Undesirable effects**

In healthy animals no clinical reactions.  
Slight transient reaction at the site of injection may occur.

**Special precaution(s) for use**

Shake well before use. Use sterile syringes and needles. Before using vaccine allow it to reach room temperature.

**5.5 Interaction with other veterinary medicinal products and other forms of interaction**

Unknown

### **5.6 Posology and method of administration**

The vaccine is a liquid product ready to be used. Shake well before use. The vaccine is administered subcutaneously into the lower back part of the neck or intramuscularly in the breast. Vaccinate animals between 8-10 days of age. Laying hens and breeders should get a second vaccination 6-10 weeks after first vaccination.

Subcutaneous or intramuscular injection of 0.5 ml is advised. For poultry upto an age of 6 weeks a dose of 0.25 ml.

### **5.7 Overdose (clinical signs, emergency procedures, antidote)**

Not different from single dose (see 5.3)

### **5.8 Special warnings for target species**

None

### **5.9 Withdrawal period**

None

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

If accidental self-administration (or bystander) occurs, a local reaction may be seen. It is recommended to seek physician's advice. Inform physician that vaccine is inactivated and is a water-in-oil emulsion.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 Incompatibilities**

No incompatibilities are known. It is not recommended to mix with other veterinary medicinal products.

### **6.2 Shelf life**

36 months

### **6.3 Special precautions for storage**

Store at 2 to 8°C. Do not freeze

### **6.4 Nature and content of container**

Sterile polyethylene terephthalate vials containing 1000 doses of 0.5 ml.

### **6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from such veterinary medicinal products**

No special precautions are required.

Dispose of according to National requirements.

## **7. CONDITION OF SUPPLY OF THE VETERINARY MEDICINAL PRODUCT TO ANIMAL OWNERS**

According to National requirements