

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Nobilis Marexine CA 126

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

<b>Active ingredients</b>	<b>per dose</b>
Live Turkey Herpes virus strain FC126	$\geq 3.0 \log_{10}$ PFU

#### **Excipients:**

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Deep frozen suspension for injection after dilution and solvent

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Chickens

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

For the active immunisation of chickens to prevent mortality, clinical signs and/or lesions after Marek's disease.

#### **4.3 Contra-indications**

None

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

None

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

##### **i. Special precautions of use in animals**

Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

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

The operator should be aware of the general precautions to be taken when handling liquid nitrogen and/or material at very low temperature. Ampoules may explode on sudden temperature changes; therefore the operator should protect himself with gloves and a visor. When removing an ampoule from a cane hold the palm of a gloved hand away from body and face. After handling vaccine operators should wash and disinfect hands with an approved disinfectant.

*First aid treatment of frost bite injuries:* Warm affected part by immersion in water at  $29 \pm 1^{\circ}\text{C}$  or use body heat. There will be considerable pain during warming, but this is normal.

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

None

#### **4.7 Use during pregnancy, lactation or lay**

Not to be used for birds in lay.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Nobilis Marexine CA 126 can be co-administered with Nobilis Rismavac if the combination vaccine Nobilis Rismavac + CA 126 is unavailable. 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**

Use the contents of one ampoule of vaccine per bottle of solvent for the indicated number of chickens. Inject 0.2 ml reconstituted vaccine to each bird subcutaneously in the neck or intramuscularly in the leg using a 20g x 1/2" needle with an approved repeating syringe or automatic vaccinator. Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.

The recommended age for injection is day-old but Nobilis Marexine CA126 can be effectively administered to birds up to three weeks of age.

##### *Reconstitution:*

Reconstitute the vaccine in Solvent for cell associated poultry vaccines, allowing 1000 doses of vaccine to each 200 ml. Prior to reconstitution the vaccine is thawed. Great care should be taken - see operator warnings.

Remove one ampoule from the cane and immediately replace the cane in the liquid nitrogen canister. Thaw the contents of the ampoule rapidly by immersing in water at room temperature. Do not thaw in hot or ice-cold water. Dry the ampoule and shake to disperse contents.

After thawing open the ampoule immediately and draw the entire contents into a sterile 5 - 10 ml syringe using an 18 gauge needle to avoid rupturing the cells.

Insert the needle through the stopper of the solvent vial (which should be at room temperature) and draw up slowly a portion of the solvent . Add the contents of the syringe to the remaining solvent . It is important that this is done slowly, allowing the vaccine to run down the side of the bottle. Gently shake the bottle as the vaccine is being mixed. Withdraw a portion of the vaccine and use to rinse the ampoule. Inject the washing back in to the solvent vial.

The reconstituted vaccine must be handled gently and administered through wide gauge needles to avoid rupturing the cells. Fill the sterilised repeating syringe/ automatic vaccinator according to the manufacturer's instructions. The vial of reconstituted vaccine should be kept in an ice bath when not being used.

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

No adverse effects anticipated.

#### **4.11 Withdrawal periods**

Zero days

### **5. IMMUNOLOGICAL PROPERTIES**

**ATC code:** QI01AD03

**Pharmacotherapeutic group:** Immunologicals for aves, Domestic fowl, Live viral vaccines.

Vaccine contains cell associated live Turkey Herpes virus to stimulate active immunity against Marek's disease in chickens

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

**Vaccine**

Calf serum

DMSO

**Solvent**

Sucrose

Pancreatic digest of casein

Potassium dihydrogen phosphate

Phenolsulfonphthalein

Water for injections

#### **6.2 Major incompatibilities**

Do not mix with other veterinary medicinal products.

### **6.3 Shelf life**

#### **Vaccine**

Shelf life of the veterinary medicinal product as packaged for sale: 51 months  
Shelf life after dilution or reconstitution according to directions:  
2 hours when kept at +2°C to +8°C.

#### **Solvent**

Shelf life as packaged for sale: 3 years in glass bottles or polyethylene bags  
2 years in multilayer plastic bags

### **6.4 Special precautions for storage**

#### **Vaccine**

Store frozen in liquid nitrogen at a temperature below  $\leq -150^{\circ}\text{C}$   
Thawed ampoules must not be refrozen.  
Do not expose reconstituted vaccine to direct sunlight or heat.

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

#### **Vaccine**

1000 and 2000 dose ampoules of hydrolytical class type I (Ph.Eur) glass containing the cell suspension. The ampoules are heat sealed.  
The ampoules are inserted in metal canes and shipped and stored in a liquid nitrogen container.

#### **Solvent**

200, 400 and 500 ml in type II glass vials closed with a halogenobutyl rubber stopper and an aluminium crimp cap.  
200, 400, 500, 600, 800, 1000, 1200 ml in polyethylene bags  
200, 400, 500, 600, 800, 1000 ml in multilayer plastic bags  
Not all presentations may be marketed.

### **6.6 Special precautions for disposal of unused medicinal product or waste material derived from the use of such product**

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant, approved for use by the competent authorities.

## **7. MARKETING AUTHORISATION HOLDER**

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

## **8. MARKETING AUTHORISATION NUMBER**

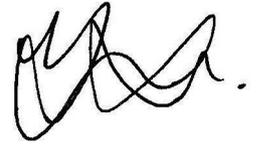
Vm 01708/4289

**9. DATE OF FIRST AUTHORISTION**

30 January 1996

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

December 2020

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 02 December 2020