

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Marek THV Iyo

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active ingredients:

##### **Vaccine**

	<u>Per dose</u>
Turkey herpesvirus strain PB-THV-1	Minimum: 1000 pfu*

The vaccine contains gentamycin as a remnant of production.

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Chickens, from one day to three weeks of age.

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

For active immunisation of chickens to reduce clinical signs and/or lesions of virulent Marek's Disease. Protection is seen by 8 days after vaccination.

##### 4.3 Contraindications

Do not use in unhealthy birds. Sick or weak birds may not develop adequate immunity following vaccination.

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

None

## 4.5 Special precautions for use

### Special precautions for use in animals

The vaccine virus may spread to susceptible, 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.

Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

Under certain conditions, for example extreme disease pressure, fully immune birds may succumb to disease.

Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

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

In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention showing a copy of the product literature.

## 4.6 Adverse reactions (frequency and seriousness)

None known

## 4.7 Use during pregnancy, lactation or lay

Not applicable

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

No information is available on the safety and efficacy of the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 7 days before or after vaccination with this product

## 4.9 Amounts to be administered and administration route

For administration to chickens from 1 day to 3 weeks of age. It is preferable to vaccinate at one day of age, however the vaccine can be effectively administered to birds up to three weeks old. For further information regarding the use of this vaccine in specific circumstances contact Intervet technical staff.

*Reconstitution:* Reconstitute the vaccine immediately before use by transferring about 2.0 ml of diluent to the vaccine vial using a sterile needle and syringe. Agitate the vial to ensure the powder plug is fully dissolved and syringe the entire contents into the diluent vial to mix with the remaining diluent.

Recommended diluent for this vaccine is Unisolve (VPA 10996/157/1)

### *Administration*

Administer by a single injection of 0.2 ml subcutaneously in the neck or intramuscularly in the leg, after reconstitution in the diluent. Injection should be made using an approved repeating syringe or automatic vaccinator. A needle of 20g x 1/2" should be used to inject the birds.

250 doses of vaccine reconstituted with 50 ml diluent

1000 doses of vaccine reconstituted with 200 ml diluent

2000 doses of vaccine reconstituted with 400 ml diluent

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

No symptoms

#### **4.11 Withdrawal Period(s)**

Zero days

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

QI01AD Live avian herpes virus vaccine.  
To stimulate active immunity against Marek's Disease.

### **6 PHARMACEUTICAL PARTICULARS**

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

Sucrose  
Bovine serum albumin  
Monobasic potassium phosphate  
Disodium phosphate dihydrate  
Monosodium glutamate  
Water for injections

#### **6.2 Incompatibilities**

Do not mix with any other vaccine/immunological product except Unisolve

#### **6.3 Shelf-life**

Freeze dried vaccine: 24 months.  
Reconstituted vaccine should be used within 2 hours.

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

Store vaccine between +2 and +8°C. Do not freeze. Protect from light  
The diluent Unisolve should not be stored above 25°C.

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

Vaccine:  
Cartons of 1 or 10 glass vials (Ph.Eur type II) containing 250, 1000 or 2000 doses of vaccine, closed with halogenobutyl rubber stoppers (Ph.Eur.) and sealed with an aluminium cap. Not all presentations may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements

**7 MARKETING AUTHORISATION HOLDER**

Intervet Ireland Ltd.  
Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10996/137/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

8<sup>th</sup> December 2003