

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Poulvac Marek CVI + HVT to be suspended in Poulvac Marek Diluent

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

#### **Poulvac Marek CVI + HVT**

##### **Active Ingredient (per dose)**

Live Marek's disease virus, strain CVI 988, cell associated: not less than  $10^{2.9}$  CCID<sub>50</sub>

Live Marek HVT strain F#126, cell associated: not less than 1000 PFU

##### **Constituents (per dose)**

- Dimethylsulphoxide	0.21 µl
- Foetal calf serum	0.21 µl
- Freezing medium	ad 2.05 µl*

\*Consisting of tryptose phosphate broth, Medium 199, amino acids, vitamins, salts, glutamine, nitric acids, dextrose and phenol red per 1,000 dose – pro rata for 2,000 dose.

#### **Poulvac Marek Diluent**

	Dose volume	
	0.2 ml	0.5 ml
- Sucrose	10.25 mg	25.62 mg
- Potassium dihydrogen phosphate	0.10 mg	0.26 mg
- Potassium monohydrogen phosphate	0.25 mg	0.63 mg
- Peptone (NZ amine)	3.00 mg	7.50 mg
- Amaranth* (E123)	4.00 µg	10.00 µg
- Aqua ad injectabilia	ad 0.20 ml	0.50 ml
*In case Phenol Red is used	2.00 µg	5.00 µg

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Frozen virus-infected cell suspension, after thawing to be diluted in Poulvac Marek Diluent.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

One day old chicks.

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

Vaccination of healthy chickens to reduce mortality and lesions caused by Marek's Disease.

### **4.3 Contraindications**

Do not vaccinate unhealthy chickens. Avoid early exposure of chicks to Marek's disease to allow for development of protection. No more than one single dose of vaccine should be administered to one day old chicks only.

### **4.4 Special warnings**

The vaccine viruses have the potential to spread. All chickens on a site should be vaccinated. In a study in highly susceptible Rhode Island Red birds, vaccine virus was shown to increase in virulence after 10 passages.

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

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

Exposure to heat and direct sunlight must be avoided.  
Contact with disinfectants makes the vaccine ineffective.  
Use clean materials for vaccination.  
Avoid vaccination of stressed animals.  
Avoid injection into or near joints and tendons.

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

To avoid all possible risks of working with liquid nitrogen and/or explosion of glass ampoules, the following precautions must be taken:

Use of gloves.  
Use of facial protection or safety goggles.  
Use of skin-covering clothing.

Operator Warnings: Liquid nitrogen causes serious freeze burns and thawing ampoules may occasionally explode after removal from the liquid nitrogen.

Operators must protect their face with a visor or goggles and hands with gloves, when handling liquid nitrogen containers and when thawing ampoules. If liquid nitrogen is spilt and comes into contact with skin causing frostbite injuries immediately:

Warm affected area by immersion in water at  $29 \pm 1^\circ\text{C}$  or by the use of body heat. Considerable pain will be experienced during warming but this is normal. Do not rub the affected area. Seek medical advice if full function and feeling are not rapidly restored.

After handling vaccine, operators should wash and disinfect their hands with an approved disinfectant.

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

None (if vaccinated according to recommended methods).

#### **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 from the concurrent use of this vaccine with any other except Poulvac IB Primer and Poulvac NDW. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

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

One dose (0.2 intramuscularly or 0.5 subcutaneously) per chicken. The vaccine is to be administered intramuscularly in one of the leg muscles or subcutaneously in the neck.

Use within 2 hours of reconstitution.

Dilution of vaccine: Reconstitute each 1,000 doses with 200 ml of diluent.

2,000 dose vials should be reconstituted in 400 ml of diluent. To administer subcutaneously, dilute 1,000 doses in 500 ml of diluent. Dilution should be done under sterile conditions with diluent at room temperature. An ampoule may occasionally explode after it has been taken out of liquid nitrogen so goggles should be worn.

Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of diluent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane. Special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct diluent is used.

Take the ampoule of vaccine out of the container of liquid nitrogen into a bowl containing clean tepid water (temperature 27°C (80°F) and not higher than 37°C (98°F)). Thaw the vaccine concentrate by carefully turning the ampoule, then remove from the water and dry the ampoule. The thawed vaccine concentrate must be used immediately.

Break the ampoule and withdraw the total contents carefully into a 10 ml sterile disposable syringe, using an 18G x 1 and a half inch (1.2 x 40 mm) or larger gauge needle. Slowly withdraw about 8 ml of diluent into the syringe. Turn the syringe 5-10 times to mix the contents well. Slowly transfer a small volume of the mixture into the empty vaccine ampoule in order to remove the last remnants of the vaccine and withdraw this small amount back into the syringe, and carefully transfer the entire contents of the syringe into the diluent bottle. Rotate the bottle about 10 times to mix the contents well. The bottle of diluent should be kept closed throughout the procedure.

The vaccine is now ready for use.

#### Administration

Poulvac Marek CVI + HVT may be administered either manually, preferably by using a multi-dose syringe dose and fitted with a 23G x 1 inch (0.60 x 25 mm) needle, or by a vaccination machine.

Administer the vaccine intramuscularly into the thigh muscle or subcutaneously in the neck.

NB During vaccination procedure, rotate the bottle of reconstituted vaccine solution every 5 minutes to prevent the cells from sedimenting.

Use within 2 hours of reconstitution.

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

The vaccine has shown to be safe in ten-fold times the recommended dose. No emergency procedure has been described.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

The vaccine is intended for use in healthy chickens for the protection against Marek's Disease.

ATC Vet Code: QI01AD03

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### **Poulvac Marek CVI + HVT**

Dimethylsulphoxide  
Bovine calf serum  
L-glutamine  
DMEM

#### **Poulvac Solvent**

Sucrose  
Potassium dihydrogen phosphate  
Potassium monohydrogen phosphate  
Peptone (NZ amine)  
Amaranth\* (E123)  
Aqua ad injectabilia

\*In case Phenol Red is used

### **6.2 Incompatibilities**

Do not mix with any other vaccine/immunological product except Poulvac Solvent.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale:

Poulvac Marek CVI + HVT:	30 months
Poulvac Solvent:	24 months

Following reconstitution, the vaccine should be stored at +2°C to +8°C and used within 2 hours.

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

The vaccine is to be stored at -196°C in a container with liquid nitrogen. Store the solvent at room temperature or at +2°C to +8°C in the dark. Avoid exposure to heat and/or direct sunlight. Once thawed, the vaccine cannot be refrozen.

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

#### **Poulvac Marek CVI + HVT**

Nature: glass ampoule  
Contents: 2 ml (1000 or 2000 dose)

The ampoules are stored in liquid nitrogen containers in a cane. The dose presentation is presented on the extremity of each cane.

Poulvac Solvent

Glass bottles

Nature: Type II hydrolytic glass bottles (Ph.Eur.) with rubber stoppers (Ph.Eur.) and aluminium overseal

Contents: 200 ml, 400 ml or 500 ml

Collapsible plastic bag

Nature: Pouch body: Draka 3250, 3256 or NM80

Filling tube: Draka 3260

Sep port: Draka 3286

Needle guide: Draka 3244

Stopper: Burnet stopper

Additive port: Draka 3286

Contents: 200 ml, 400 ml, 500 ml, 600 ml, 800 ml or 1 litre

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**

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

**7. MARKETING AUTHORISATION HOLDER**

Zoetis UK Limited  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

**8. MARKETING AUTHORISATION NUMBER**

Vm 42058/4108

**9. DATE OF FIRST AUTHORISATION**

24 May 1999

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

October 2024

*Gavin Hall*  
Approved: 10 April 2025