Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek CVI + HVT.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose of 0.2 ml contains:

Active substances:
Live Marek's disease virus, strain CVI 988, cell associated: not less than $10^{2.9}$ $CCID_{50}$, not more than $10^{3.5}$ $CCID_{50}$*.
Live Marek HVT strain F#126, cell associated: not less than 1000 PFU, not more than 6000 PFU**

*$CCID_{50}$ = cell culture 50% infective dose
**PFU = plaque forming units

Excipient(s):

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

Chicken.

4.2 Indications for use, specifying the target species

Active immunisation of healthy day-old chicks against Marek's Disease to reduce mortality, clinical signs and lesions of the disease.
Onset of immunity: 9 days post vaccination.

4.3 Contraindications

Do not use in unhealthy chickens.

4.4 Special warnings for each target species

The vaccine viruses have the potential to spread. After 10 passages the vaccine showed an increase in virulence in the highly susceptible pure bred Rhode Island Red bird. Maternal antibodies may have some negative influence on vaccination.

4.5 Special precautions for use

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.
Do not vaccinate in an infected environment.

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.
In case of accidental self-injection seek medical advice immediately and show the package insert or label to the physician.
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.
Seek medical advice in the event of a liquid nitrogen burn.
After handling the vaccine, operators should wash and disinfect their hands with an approved disinfectant.

4.6 Adverse reactions (frequency and seriousness)

None.

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 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

Posology:
One dose of vaccine suspended in 0.2 ml of accessory diluent.

Route of administration:
Intramuscularly in one of the leg muscles or subcutaneously in the neck.

Preferably a 21 G x 1" (0.8 mm x 2.5 cm) needle should be used. Contact with disinfectants makes the vaccine ineffective. Work aseptically and use clean materials for vaccination.

Once the vaccine has been removed from the nitrogen, prevent the vaccine from refreezing or exposure to heat and / or direct sunlight.

Vaccination schedule:
One vaccination of one-day old chickens using one dose of vaccine per bird.

Dilution of vaccine:
Reconstitute each 1,000 doses with 200 ml of diluent. Each 2,000 doses of vaccine should be diluted in 400 ml of diluent. Dilution should be done under aseptic conditions. An ampoule may occasionally explode after it has been taken out of the liquid nitrogen container. Therefore, safety measures must be taken (see 4.5). Take the ampoule of vaccine out of the liquid nitrogen container into a bowl containing clean tepid water (temperature between 12 ºC and 22 ºC). Thaw the vaccine 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 18 G x 1 and a half inch (1.2 x 40 mm) or larger gauge needle. Slowly draw about 8 ml of diluent into the syringe. Turn the syringe 5-10 times to mix the content 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. Carefully transfer the entire contents of the syringe into the diluent container. Rotate the bottle about 10 times to mix the contents well. The vaccine is now ready for use within 2 hours.

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

No available data.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI01AD03

The vaccine contains a Marek's disease virus, strain CVI 988, an attenuated and homologous strain, and a turkey herpes virus strain HVT 126, a heterologous strain non-pathogenic for poultry. The vaccination induces an active immunity against Marek's disease in one-day old chickens, which is demonstrated by challenge at 9 days after vaccination.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poulvac Marek CVI + HVT
Dimethylsulphoxide
Foetal calf serum
Freezing medium

Poulvac Marek Diluent
Sucrose
Potassium dihydrogen phosphate
Dipotassium phosphate
Peptone (NZ amine)
Phenolsulphonphthalein (phenol red)
Water for injections

6.2 Incompatibilities

Do not mix with any other product except Poulvac Marek Diluent.

6.3 Shelf-life

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

Poulvac Marek CVI+HVT:		24 months
Poulvac Marek Diluent:	glass bottle:	36 months
Poulvac Marek Diluent:	plastic bag:	24 months

Following suspending, the vaccine should be used within 2 hours.

6.4 Special precautions for storage

Avoid exposure to heat and/or direct sunlight.
Vaccine: at -196ºC in liquid nitrogen.
Once thawed, the vaccine cannot be refrozen. Diluent: at room temperature (15 to 25ºC).

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:

Vaccine:
Type I glass ampoules sealed by fusion

Diluent:
Type II glass bottle containing 200ml or 400ml.
PVC plastic bags containing 200ml, 400ml or 1000ml.

Packaging intended for sale:

Vaccine:
Liquid nitrogen containers of n 1000 – dose ampoules
Liquid nitrogen containers of n 2000 – dose ampoules

Diluent:
Carton box containing 10 bottles or plastic bags

Not all pack sizes 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 approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as: Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/177/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th November 2004

10 DATE OF REVISION OF THE TEXT

May 2012