IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

10019/178/001
Case No: 7007814

Transferred from 10861/061/001.

The Irish Medicines Board in exercise of the powers conferred on it by the Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to: **Pfizer Healthcare Ireland**

Ringaskiddy, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Poulvac Marek HVT

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said schedule.

The authorisation,unless revoked, shall continue in force from **14/05/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek HVT.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	per 0.2 ml dose
Marek HVT strain F#126	Minimum ≥ 1000 PFU*
	Maximum ≤ 6000 PFU*

*PFU = Plaque Forming Units

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for reconstitution for solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Day old chickens.

4.2 Indications for use, specifying the target species

For active immunisation of chickens to reduce lesions of Marek's Disease.
The onset of immunity occurs two weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate diseased chickens.
Do not vaccinate in an infected environment.
Do not inject into or near joints or tendons.
Maternally derived antibody (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.

4.5 Special precautions for use

Special precautions for use in animals

Contact with disinfectants renders the vaccine inactive.
Use clean materials for vaccination.
The vaccine virus may spread to in contact birds. It is recommended that all birds on a site be vaccinated

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

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 compatibility of this vaccine with any other.
Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

One dose of 0.2ml per chicken.
The vaccine is to be administered intramuscularly in the thigh.
For administration of the vaccine an automatic syringe with a 23 gauge x 1 inch needle is recommended

100ml bottle of diluent is used to reconstitute 500 doses of vaccine.
200ml bottle of diluent is used to reconstitute 1,000 doses of vaccine.
400 ml bottle of diluent is used to reconstitute 2,000 doses of vaccine.
1L plastic bag of diluent is used to reconstitute 5,000 doses of vaccine.

Cleanse rubber stoppers with alcohol and allow to dry. Using a sterile needle and syringe, insert through diluent bottle stopper and withdraw 3 ml of diluent. Transfer by inserting through vaccine vial stopper. After slight agitation of the vial to ensure that the vaccine has dissolved, insert needle and withdraw entire contents into the syringe. Remove the syringe containing all the reconstituted vaccine from vial and re-insert into diluent bottle. Expel syringe contents into diluent.

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

The vaccine has been shown to be safe at ten times the recommended dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Marek's Disease Virus.

ATC Vet code: QI01AD03

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Sucrose
Monosodium glutaminate
Potassium Phosphate monobasic
Potassium Phosphate dibasic
Ethylenediaminetetra-acetic acid (EDTA)
Bovine serum albumin fraction V

Solvent:
Sucrose
Potassium dihydrogen phosphate
Potassium monohydrogen phosphate
Peptone (NA amine)
Phenolsulphonuphtalein

6.2 Incompatibilities

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

6.3 Shelf-life

Poulvac Marek HVT: 24 months
Poulvac Marek Diluent: 24 months
After reconstitution the vaccine should be used immediately.

6.4 Special precautions for storage

Vaccine:

Store in a refigerator 2 ºC - 8 ºC. Protect from light.

Solvent:

Do not store above 25 ºC. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Vaccine: The container is a 6 or 10 ml Type 1 Borosilicate glass bottle closed with a sterile 20 mm fluted chlor-butyl-rubber stopper.
Fill volume in a 6 ml glass vial is 1.0 ± 0.2 ml for the 500 dose bottle and 2.0 ml ± 0.2 ml in a 10 ml glass vial for the 1000 or 2000 dose bottles.

Poulvac Marek Diluent: Glass Type II bottle for 100, 200, 400 ml volumes
Plastic bag for 1 litre volume.

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

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/178/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th November 2007

10 DATE OF REVISION OF THE TEXT

14th May 2010