

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Poulvac MD Vac – Outer Label**

10x 500 dose  
10x 1000 dose  
10x 2000 dose

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

Poulvac MD Vac Lyophilisate and diluent for suspension for injection for chickens.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Marek HVT strain F#126 2,250-17,500 PFU per 0.2 ml dose.

**3. PHARMACEUTICAL FORM**

Lyophilisate and diluent for suspension for injection.

**4. PACKAGE SIZE**

10 x 500 doses  
10 x 1,000 doses  
10 x 2,000 doses

**5. TARGET SPECIES**

Chickens.

**6. INDICATION(S)**

To prevent mortality and clinical signs due to infection with Marek's disease virus.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

One dose of 0.2 ml per chicken.

The vaccine is to be administered either by intramuscular injection in the thigh or by subcutaneous injection in the neck to one-day-old chickens.

**8. WITHDRAWAL PERIOD(S)**

**Withdrawal period:** Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

Following dilution the dissolved vaccine should be kept at room temperature and used within 2 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport at +2°C to +8°C.  
Protect from light. Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For Animal Treatment Only.

POM-VPS

To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Marketing Authorisation Holder:**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 42058/5206

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Poulvac MD Vac – Vial Label**

500 doses  
1000 doses  
2000 doses

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

Poulvac MD Vac

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Marek HVT strain F#126 2,250-17,500 PFU per 0.2 ml dose.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

500 doses  
1,000 doses  
2,000 doses

**4. ROUTE(S) OF ADMINISTRATION**

I.M. S.C.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

EXP:  
Once reconstituted use within 2 hours.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**For animal treatment only.**

Vm 42058/5206  
Zoetis UK Limited

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Poulvac MD Vac Lyophilisate and diluent for suspension for injection**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain, S.L.  
Ctra. Camprodón s/n "la Riba"  
17813 Vall de Bianya, Girona,  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Poulvac MD Vac

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Marek HVT strain F#126 2,250-17,500 PFU per 0.2 ml dose.

**4. INDICATION(S)**

To prevent mortality and clinical signs due to infection with Marek's disease virus. Onset of immunity has been demonstrated from 5 days after vaccination. No information is available on the duration of the protection elicited by vaccination. However, experience in the field suggests that Marek's disease vaccine virus strains and antibody titres persist for up to 2 years after vaccination.

**5. CONTRAINDICATIONS**

Do not use in sick chickens.  
Do not vaccinate in an infected environment.  
Do not use in birds in lay.

**6. ADVERSE REACTIONS**

No local or systemic reactions have been observed following the administration of the vaccine during safety studies. However, and in common with other immunological products, it is expected that local or systemic reactions may occur in a very small proportion of vaccinated birds.

## **7. TARGET SPECIES**

Chickens.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

One dose of 0.2 ml per chicken.

The vaccine is to be administered either by intramuscular injection in the thigh or by subcutaneous injection in the neck to one-day-old chickens.

Reconstitute each 1,000 doses of Poulvac MD-Vac with 200 ml of diluent at room temperature. Remove the centre tabs of aluminium seals on both vaccine vial and diluent bottle, leaving intact the outer ring on both vial and bottle. Cleanse rubber stoppers with alcohol and allow to dry. All equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants. 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. The reconstituted vaccine is now ready for use. For administration of the vaccine an automatic syringe with a 23 gauge x 1 inch (0.60 x 25 mm) needle is recommended. Inject each chick intramuscularly with 0.2 ml of vaccine, the usual site being the upper thigh, or subcutaneously in the neck. Use within 2 hours of reconstitution.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Avoid exposure to heat or direct sunlight.

Avoid contact with disinfectants as this renders the vaccine inactive.

Use clean materials for vaccination.

Avoid stress in chickens before and after vaccination.

Avoid injection into or near joints and tendons.

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

### Poulvac MD Vac

Store and transport at +2°C to +8°C.

Protect from light. Do not freeze.

### Poulvac Solvent

Store and transport at room temperature or at +2°C to +8°C in the dark.

Avoid exposure to heat and/or direct sunlight.

Do not freeze.

Following dilution the dissolved vaccine should be kept at room temperature and used within 2 hours.

## **12. SPECIAL WARNING(S)**

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Poulvac IBMM, Poulvac Hitchner B1 and Poulvac Bursine 2.

The products should be given at different sites.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

Do not mix with any other veterinary medicinal product, except diluent supplied.

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.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

## **14. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **15. OTHER INFORMATION**

For Animal Treatment Only

### **PACKAGE QUANTITIES**

Poulvac MD Vac

10 x 500, 1000 and 2000 dose.

Poulvac Solvent

Glass bottles of 200 ml, 400 ml or 500 ml.

Collapsible plastic bag of 200 ml, 400 ml, 500 ml, 600 ml, 800 ml or 1 litre.

Not all pack sizes may be marketed.

**LEGAL CATEGORY**

**POM-VPS**

Prescription Only Medicine – Veterinarian, Pharmacist, SQP

To be supplied only on veterinary prescription

**MARKETING AUTHORISATION NUMBER**

Vm 42058/5206

*Gavin Hall*

Approved: 05 December 2025