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 42058/4109

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.

Vm42058/4109
Zoetis UK Limited, Surrey

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 Marek Diluent
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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

For Animal Treatment Only

PACKAGE QUANTITIES
Poulvac MD Vac
10 x 500, 1000 and 2000 dose.

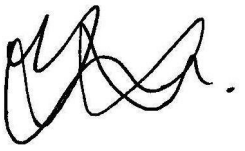
Poulvac Marek Diluent
Glass bottles of 200 ml, 400 ml or 500 ml.
Collapsible plastic bag of 200 ml, 400 ml, 500 ml, 600 ml, 800 ml or 1 litre.
Not all pack sizes may be marketed.

LEGAL CATEGORY
POM-VPS
Prescription Only Medicine – Veterinarian, Pharmacist, SQP

To be supplied only on veterinary prescription

MARKETING AUTHORISATION NUMBER

Vm42058/4109



Approved: 27 July 2022