SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac MD Vac Lyophilisate and Diluent for Suspension for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Marek's disease vaccine (live).

Quantitative composition

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and diluent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings

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, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

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.

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

None.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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.

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

No local or systemic reactions have been observed after the administration of a tenfold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine induces active immunity against Marek's disease virus.
ATC Vet Code: QI01AD03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine
Sucrose
Monopotassium phosphate
Dipotassium phosphate

Monosodium glutamate
Bovine albumin powder

Diluent
Sucrose
Potassium dihydrogen phosphate
Potassium monohydrogen phosphate
Peptone (NZ amine)
Phenylsulphonophthalein (phenol red)
Water for injection

6.2 Incompatibilities

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

6.3 Shelf life

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

Poulvac MD-Vac: 2 years and 3 months.
Poulvac Solvent: 2 years.

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

6.4 Special precautions for storage

Poulvac MD-Vac
Store and transport at +2ºC to +8ºC. Protect from light. Do not freeze.
Poulvac Solvent
Store and transport at room temperature or at +2ºC to +8ºC in the dark. Avoid exposure to heat and/or direct sunlight. Do not freeze.

6.5 Nature and composition of immediate packaging

Poulvac MD-Vac

Nature: Hydrolytic Type I Glass (Ph.Eur.) vials with butyl rubber stoppers (Ph.Eur.) and aluminium overseal

Contents: 1.0 ± 0.2 ml for 500 dose presentation; 2.0 ± 0.2 ml for 1000 and 2000 dose presentations.

Poulvac Solvent

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

Contents: 200 ml, 400 ml and 500 ml.

Plastic Bags

Nature:	Pouch body Draka 3250, 3256 or NM80
Filling tube	Draka 3260
Set port	Draka 3286
Needle guide	Draka 3244
Stopper	Burnet Rubber
Additive port	Draka 3286
Contents:	200 ml, 400 ml, 500 ml, 600 ml, 800 ml and 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, if appropriate

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 42058/5206

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 05 December 2025