SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek CVI + HVT to be suspended in Poulvac Marek Diluent

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Poulvac Marek CVI + HVT

Active Ingredient (per dose)
Live Marek's disease virus, strain CVI 988, cell associated: not less than $10^{2.9}$ $CCID_{50}$
Live Marek HVT strain F#126, cell associated: not less than 1000 PFU

Constituents (per dose)

- Dimethylsulphoxide	0.21 µl
- Foetal calf serum	0.21 µl
- Freezing medium	ad 2.05 µl*

*Consisting of tryptose phosphate broth, Medium 199, amino acids, vitamins, salts, glutamine, nitric acids, dextrose and phenol red per 1,000 dose – pro rata for 2,000 dose.

Poulvac Marek Diluent

		Dose volume	
		0.2 ml	0.5 ml
- Sucrose		10.25 mg	25.62 mg
- Potassium dihydrogen phosphate		0.10 mg	0.26 mg
- Potassium monohydrogen phosphate		0.25 mg	0.63 mg
- Peptone (NZ amine)		3.00 mg	7.50 mg
- Amaranth* (E123)		4.00 µg	10.00 µg
- Aqua ad injectabilia	ad	0.20 ml	0.50 ml
*In case Phenol Red is used		2.00 µg	5.00 µg

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

One day old chicks.

4.2 Indications for use, specifying the target species

Vaccination of healthy chickens to reduce mortality and lesions caused by Marek's Disease.

4.3 Contraindications

Do not vaccinate unhealthy chickens. Avoid early exposure of chicks to Marek's disease to allow for development of protection. No more than one single dose of vaccine should be administered to one day old chicks only.

4.4 Special warnings

The vaccine viruses have the potential to spread. All chickens on a site should be vaccinated. In a study in highly susceptible Rhode Island Red birds, vaccine virus was shown to increase in virulence after 10 passages.

4.5 Special precautions for use

i. 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.

ii. 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.

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. If liquid nitrogen is spilt and comes into contact with skin causing frostbite injuries immediately:
Warm affected area by immersion in water at 29 ± 1°C or by the use of body heat. Considerable pain will be experienced during warming but this is normal. Do not rub the affected area. Seek medical advice if full function and feeling are not rapidly restored.
After handling vaccine, operators should wash and disinfect their hands with an approved disinfectant.

4.6 Adverse reactions (frequency and seriousness)

None (if vaccinated according to recommended methods).

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 from the concurrent use of this vaccine with any other except Poulvac IB Primer and Poulvac NDW. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

One dose (0.2 intramuscularly or 0.5 subcutaneously) per chicken. The vaccine is to be administered intramuscularly in one of the leg muscles or subcutaneously in the neck.
Use within 2 hours of reconstitution.
Dilution of vaccine: Reconstitute each 1,000 doses with 200 ml of diluent. 2,000 dose vials should be reconstituted in 400 ml of diluent. To administer subcutaneously, dilute 1,000 doses in 500 ml of diluent. Dilution should be done under sterile conditions with diluent at room temperature. An ampoule may occasionally explode after it has been taken out of liquid nitrogen so goggles should be worn.
Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of diluent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane. Special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct diluent is used.

Take the ampoule of vaccine out of the container of liquid nitrogen into a bowl containing clean tepid water (temperature 27°C (80°F) and not higher than 37°C (98°F)). Thaw the vaccine concentrate 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 18G x 1 and a half inch (1.2 x 40 mm) or larger gauge needle. Slowly withdraw about 8 ml of diluent into the syringe. Turn the syringe 5-10 times to mix the contents 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, and carefully transfer the entire contents of the syringe into the diluent bottle. Rotate the bottle about 10 times to mix the contents well. The bottle of diluent should be kept closed throughout the procedure.
The vaccine is now ready for use.

Administration
Poulvac Marek CVI + HVT may be administered either manually, preferably by using a multi-dose syringe dose and fitted with a 23G x 1 inch (0.60 x 25 mm) needle, or by a vaccination machine.
Administer the vaccine intramuscularly into the thigh muscle or subcutaneously in the neck.
NB During vaccination procedure, rotate the bottle of reconstituted vaccine solution every 5 minutes to prevent the cells from sedimenting.
Use within 2 hours of reconstitution.

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

The vaccine has shown to be safe in ten-fold times the recommended dose.
No emergency procedure has been described.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine is intended for use in healthy chickens for the protection against Marek's Disease.

ATC Vet Code: QI01AD03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poulvac Marek CVI + HVT
Dimethylsulphoxide
Bovine calf serum
L-glutamine
DMEM

Poulvac Solvent
Sucrose
Potassium dihydrogen phosphate
Potassium monohydrogen phosphate
Peptone (NZ amine)
Amaranth* (E123)
Aqua ad injectabilia

*In case Phenol Red is used

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product except Poulvac Solvent.

6.3 Shelf life

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

Poulvac Marek CVI + HVT:	30 months
Poulvac Solvent:	24 months

Following reconstitution, the vaccine should be stored at +2°C to +8°C and used within 2 hours.

6.4 Special precautions for storage

The vaccine is to be stored at -196°C in a container with liquid nitrogen. Store the solvent at room temperature or at +2ºC to +8ºC in the dark. Avoid exposure to heat and/or direct sunlight. Once thawed, the vaccine cannot be refrozen.

6.5 Nature and composition of immediate packaging

Poulvac Marek CVI + HVT
Nature: glass ampoule
Contents: 2 ml (1000 or 2000 dose)

The ampoules are stored in liquid nitrogen containers in a cane. The dose presentation is presented on the extremity of each cane.

Poulvac Solvent
Glass bottles
Nature: Type II hydrolytic glass bottles (Ph.Eur.) with rubber stoppers (Ph.Eur.) and aluminium overseal
Contents: 200 ml, 400 ml or 500 ml

Collapsible plastic bag

Nature: Pouch body:	Draka 3250, 3256 or NM80
Filling tube:	Draka 3260
Sep port:	Draka 3286
Needle guide:	Draka 3244
Stopper:	Burnet stopper
Additive port:	Draka 3286

Contents: 200 ml, 400 ml, 500 ml, 600 ml, 800 ml or 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

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
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5223

9. DATE OF FIRST AUTHORISATION

24 May 1999

10. DATE OF REVISION OF THE TEXT

December 2025

Gavin Hall
Approved: 18 December 2025