SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek CVI.
(To be suspended in Poulvac Marek Diluent)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.2 ml contains:

Active substance:

Live Marek's disease virus (MDV), strain CVI 988, cell associated: ≥ 250 $CCID_{50}$*

*$CCID_{50}$ = 50 % cell culture infective dose

Excipient(s):

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Frozen virus-infected cell suspension and diluent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

One day old chickens.

4.2 Indications for use, specifying the target species

For the active immunisation of chickens to reduce mortality and lesions caused by Marek's Disease.
The onset of immunity is from 9 days of vaccination and the duration of immunity is not known but has been shown by challenge to be at least 4 weeks. Vaccine virus and antibodies to Marek's disease virus have been shown to persist in vaccinated chickens for up to 2 years.

4.3 Contraindications

Do not use in sick chickens.

4.4 Special warnings

Vaccine virus spreads from bird to bird. In a study in highly susceptible Rhode Island Red birds, vaccine virus was shown to increase in virulence after ten passages.
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 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

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 frost bite 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)

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 IB H120, Poulvac NDW, Poulvac TRT and Poulvac MD Vac. In the case of products administered parenterally, 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 0.2 ml dose per chicken.
The vaccine is to be administered by intramuscular injection in the thigh muscle or by subcutaneous injection in the neck.
Dilution of vaccine:
Reconstitute The 2,000 dose presentation with 400 ml of diluent,4000 dose presentation with 800 ml of diluent and the 5,000 dose presentation with 1000 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 and cannot be refrozen.
All equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants.
Break the ampoule and withdraw the total contents carefully into a 10 ml sterile disposable syringe, using an 18G x 1.5 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 and should be used within 2 hours of reconstitution.
Administration: Poulvac Marek CVI 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 the vaccination procedure, rotate the bottle of reconstituted vaccine solution every 5 minutes to prevent the cells from sedimenting.

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 an active immunity against Marek's Disease.

ATC Vet Code: QI01AD03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poulvac Marek CVI:
Dimethylsulphoxide
Bovine calf serum
L-glutamine
DMEM

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

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Poulvac Marek Diluent and Poulvac MD Vac.

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Vaccine
Shelf-life of the veterinary medicinal product as packaged for sale: 18 months

Diluent
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Shelf-life after dilution or reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Poulvac Marek CVI
Store and transport at -196°C in a container with liquid nitrogen.

Poulvac Marek Diluent
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 Marek CVI:
Nature: Hydrolytic Type I Glass ampoules sealed by fusion.
Contents: 2,000,4000 or 5,000 doses.
The ampoules are stored in liquid nitrogen containers in a cane (5 ampoules per cane. The dose presentation is presented on the extremity of each cane.

Poulvac Marek Diluent:

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

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
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Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4107

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

July 2022

Approved: 27 July 2022