ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL) OF THE SOLVENT

Poulvac Marek Diluent
200 ml
400 ml
800 ml
1000 ml

1. NAME OF THE SOLVENT

Poulvac Marek Diluent

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

200 ml
400 ml
800 ml
1000 ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

For use with the following Marek's Disease vaccines for chickens:

Poulvac Marek CVI
Poulvac Marek HVT
Poulvac Marek HVT CA
Poulvac Marek CVI + HVT

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The contents of this pack may be used to reconstitute ---- doses of vaccine, in which case the dose per bird of reconstituted vaccine should be ---- ml.
IM / SC

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use entire contents when first opened.

11. SPECIAL STORAGE CONDITIONS

Store below 25°C.
Protect from light.

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4108

17. MANUFACTURER'S BATCH NUMBER

<Lot>{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1000 dose ampoules
2000 dose ampoules

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek CVI + HVT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

MDV ≥ $10^{2.9}$ $CCID_{50}$/ds, HVT ≥ 1000 PFU/ds

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

1000 ds
2000 ds
(number of doses per ampoule is presented on the extremity of each cane containing the ampoule)

4. ROUTE(S) OF ADMINISTRATION

IM / SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

<Lot> {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us Vet

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Poulvac Marek CVI + HVT

Concentrate and solvent for suspension for injection, for chickens.

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
C/Camprodon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Marek CVI + HVT
Concentrate and solvent for suspension for injection, for chickens.

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

One dose of 0.2 ml contains:

Active substances:
Live Marek's disease virus (MDV), strain CVI 988, cell associated: **≥** $10^{2.9}$ $CCID_{50}$*
Live turkey herpes virus (HVT), strain FC-126, cell associated: **≥** 1000 PFU**

*$CCID_{50}$ = 50% cell culture infective dose
** PFU = plaque forming units

Concentrate: Yellow to light orange frozen suspension. When thawed, light orange to light pink suspension.
Solvent: Clear and red liquid.

4. INDICATION(S)

Active immunisation of healthy one-day-old chicks against Marek's Disease to reduce mortality, clinical signs and lesions of the disease.

Onset of immunity: 9 days after vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

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

Posology:
One dose (0.2 ml) per chicken.

Route of administration:
Intramuscularly in one of the leg muscles or subcutaneously in the neck.

Preferably a 21 G x 1” (0.8 mm x 2.5 cm) needle should be used. Contact with disinfectants makes the vaccine ineffective. Work aseptically and use clean materials for vaccination.

Once the vaccine has been removed from the nitrogen, prevent the vaccine from refreezing or exposure to heat and / or direct sunlight.

Vaccination schedule:
One vaccination of one-day-old chicks using one dose of vaccine per bird.

Dilution of vaccine:
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 solvent 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 mix-ups of ampoules with different number of doses is avoided and the correct volume of solvent is used.

Reconstitute each 1,000 doses with 200 ml of solvent (2,000 doses presentation with 400 ml of solvent and the 1000 ml solvent presentation could be used for a total of 5,000 doses). Reconstitution should be done under aseptic conditions. An ampoule may occasionally explode after it has been taken out of the liquid nitrogen container. Therefore, safety measures must be taken (see Section: Special warnings).

Take the ampoule of vaccine out of the liquid nitrogen container into a bowl containing clean tepid water (temperature between 12 ºC and 22 ºC). Thaw the vaccine 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 18 G x 1.5” (1.2 mm x 40 mm) or larger gauge needle. Slowly draw about 8 ml of solvent into the syringe. Turn the syringe 5-10 times to mix the content 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. Carefully transfer the entire contents of the syringe into the solvent container. Rotate the container about 10 times to mix the contents well. The vaccine is now ready for use within 2 hours.

9. ADVICE ON CORRECT ADMINISTRATION

No more than one single dose of vaccine should be administered to one-day-old chicks only.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Poulvac Marek CVI+HVT vaccine concentrate:
Store and transport frozen at -196 °C in liquid nitrogen. Once thawed, vaccine cannot be refrozen.
Poulvac Marek Diluent: Store below 25°C. Protect from light.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
Avoid vaccination of stressed animals.
The vaccine viruses have the potential to spread. After 10 passages the vaccine showed an increase in virulence in the highly susceptible pure bred Rhode Island Red birds.
All chickens in the flock should be vaccinated at the same time.
Maternal antibodies may have some negative influence on vaccination. Avoid contact of the vaccinated chicks with feather dust of other chickens to allow development of protection.

Special precautions for use in animals:
Avoid injection into or near joints and tendons.
Only vaccinate in a clean environment devoid of feather dust.

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

Operator warnings: liquid nitrogen causes serious freeze burns and thawing ampoules may occasionally explode after removal from the liquid nitrogen. Personal protective equipment consisting of gloves, facial protection, safety goggles and skin-covering clothing should be worn when handling the veterinary medicinal product.

In case of accidental self-injection seek medical advice immediately and show the package leaflet to the physician.

Seek medical advice in the event of a liquid nitrogen burn.

After handling the vaccine, operators should wash and disinfect their hands with an approved disinfectant.

Lay:
Do not use in birds in lay and in breeding birds.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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.

Overdose (symptoms, emergency procedures, antidotes):
No data are available on symptoms after administration of an overdose.

Incompatibilities:
Do not mix with any other product except Poulvac Marek Diluent supplied for use with the veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

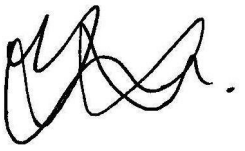
The vaccine contains a Marek's disease virus, strain CVI 988, an attenuated and homologous strain, and turkey herpes virus strain FC 126, a heterologous strain non-pathogenic for poultry. The vaccination induces an active immunity against Marek's disease in one-day-old chickens, which is demonstrated by challenge at 9 days after vaccination.

Packaging:

Poulvac Marek CVI+HVT vaccine concentrate:
Glass ampoules of 2 ml (1000 or 2000 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 bottle containing 200 or 400 ml.
PVC plastic bags containing 200, 400, 800 or 1000 ml.

Not all pack sizes may be marketed.



Approved: 27 July 2022