ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoules of 500, 1000, 2000 and 4000 doses of vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD HVT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

HVT

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

500 D
1000 D
2000 D
4000 D

(Attached to the cane is a tag displaying the doses (D) per ampoule.)

4. ROUTE(S) OF ADMINISTRATION

SC, *in ovo*

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot.: {number}

(Attached to the cane is a tag displaying the Lot. number as well.)

7. EXPIRY DATE

EXP :

Store: -196°C
Ceva-Phylaxia Co. Ltd.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT

Solvent bag, 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml

1. NAME OF THE DILUENT

Cevac Solvent Poultry

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

200 ml
400 ml
800 ml
1000 ml
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25°C.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo
or
Ceva-Phylaxia Co. Ltd.
1107 Budapest
Szállás u 5.
Hungary

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Cevac MD HVT suspension 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 and manufacturer responsible for batch release:

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release
Ceva- Phylaxia Co. Ltd.
Budapest
Szállás u 5.
1107
HUNGARY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD HVT suspension and solvent for suspension for injection for chickens

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

Each dose (0.05 ml *in ovo* or 0.2 ml subcutaneous) contains:

Cell-associated live viral turkey herpes virus (HVT, Marek's disease virus), serotype3, strain FC-126 2000-8000 PFU*
*PFU: plaque forming unit

Vaccine: yellowish-brownish, dense, frozen virus suspension.
Solvent: clear, orange to red solution.

4. INDICATION(S)

For active immunisation of 18-day-old embryonated chicken eggs or one-day-old chicks to reduce mortality, clinical signs and lesions caused by mild and virulent strains of Marek's disease virus.

Onset of immunity: 9 days after the vaccination

Duration of immunity: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Chickens and embryonated chicken eggs

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

In ovo or subcutaneous use:

In ovo:
One single injection of 0.05 ml is injected into each 18-day-old embryonated chicken egg. For *in ovo* application an automatic *in ovo* egg injector can be used. *In-ovo* equipment should be calibrated to ensure that a 0.05 ml dose is applied to each egg.

Subcutaneous use (preferably under the skin of the neck):
One single injection of 0.2 ml per chick is applied at one day of age.
The vaccine may be injected by automatic syringe. The 500 dose presentation is recommended for manual injection.
Overview table for recommended dilution possibilities of different presentations:

For *in ovo* administration:

Frozen suspension presentation No. of ampoules x doses (D)	**Solvent presentation (ml)**	**Volume of one dose (ml)**
8 x 500 D	200	0.05
8 x 1000 D	400	
4 x 2000 D	400	
2 x 4000 D	400	
4 x 4000 D	800	
5 x 4000 D	1000	
6 x 4000 D	1200	
8 x 4000 D	1600	

The speed of automatic injection is at least 2,500 eggs per hour. Solvent presentation of at least or more than 400 ml is recommended to prime the machine and inject for longer than 10 minutes.

The 200 ml solvent presentation may be used for manual *in-ovo* equipment.

For subcutaneous administration:

Frozen suspension presentation No. of ampoules x doses (D)	Solvent presentation (ml)	Volume of one dose (ml)
2 x 500 D	200	0.20
1 x 1000 D	200	
1 x 2000 D	400	
2 x 2000 D	800	
1 x 4000 D	800	
3 x 2000 D	1200	
2 x 4000 D	1600	

9. ADVICE ON CORRECT ADMINISTRATION

The usual aseptic precautions should be applied to all administration methods.
Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury

Reconstitution of the vaccine:

1. After matching the dose size of the ampoules with the solvent size, quickly remove the exact number of ampoules needed from the liquied nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe. Use minimum 18 gauge needle.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39°C.
4. As soon as they are completely thawed, open ampoules holding them at arm length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open, slowly draw up the content into the 5-ml sterile syringe prepared as in point 2.
6. Transfer the thawed suspension into the solvent bag. The reconstituted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine from the solvent bag into the syringe and use it to rinse the ampoule. Inject it gently back into the solvent bag. Repeat once or twice.
8. The reconstituted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2-7 for the appropriate number of ampoules to be thawed.
Use the reconstituted vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours.

It should be ensured that the diluted vaccine is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine remains homogenous and that the correct virus titer is administered (e.g. when automatic *in ovo* injection machines are used or during long vaccination sessions).

Do not use Cevac MD HVT if you notice visible signs of unacceptable decolourisation in the vials.
Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not re-use opened containers of diluted vaccine.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Frozen virus suspension:
Store and transport frozen in liquid nitrogen (-196°C).
The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed. Store liquid nitrogen container securely in upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

Solvent:
Store below 25°C. Do not freeze.

Shelf life after reconstitution according to directions: 2 hours at a temperature below 25°C.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals
The vaccine strain was shown to be excreted by chickens for 46 days. The excreted vaccine strain was not harmful in turkeys in safety trials; however, special precautions should be taken to avoid spreading of the vaccine strain to turkeys. A ten-fold overdose was safe for turkeys, ducks, quails, guinea fowls, pheasants and pigeons.

No spread was demonstrated between chickens.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Liquid nitrogen containers and vaccine ampoules should be handled by properly trained personnel only.
Personal protective equipment consisting of protective gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.
Frozen glass ampoules may explode during sudden temperature changes

Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.
Personnel involved in the treatment of vaccinated birds should use hygiene principles and take particular care in handling litter from vaccinated chickens.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this immunological veterinary medicinal product 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 symptoms were observed after the administration of a 10-fold dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent (Cevac Solvent Poultry) supplied for use with the product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Frozen suspension (not reconstituted vaccine):
1x glass ampoule of 2 ml containing 500, 1000, 2000 or 4000 doses of the vaccine. Ampoules are put on cane, supplied with tag showing the numbers of dose. The canes with ampoules are stored in a liquid nitrogen container.

Solvent: Polyvinylchloride bag containing 200, 400, 800, 1000, 1200, or 1600 ml of solvent in individual over-pouch.
(Lot, EXP - see back of the bag)

Not all pack sizes may be marketed.

Vm 15052/4089

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 27 September 2022