Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
Cell-associated live turkey herpes virus (HVT, Marek's disease virus),
serotype 3, strain FC-126 2000-8000 PFU*
*PFU: plaque forming unit

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection.

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

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens and embryonated chicken eggs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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 follow hygiene principles and take particular care in handling litter from vaccinated chickens.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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 2500 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	

The usual aseptic precautions should be applied to all administration procedures.
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 liquid 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).

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

No symptoms were observed after the administration of a 10-fold dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Immunologicals for aves, live viral vaccines, avian herpes virus (Marek's disease)

ATCvet code: QI01AD03

Live viral vaccine to stimulate active immunity against Marek's disease.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Frozen virus suspension:
EMEM
L-glutamine
Sodium bicarbonate
Hepes
Bovine serum
Dimethyl sulfoxide
Water for injection

Solvent (Cevac Solvent Poultry):
Sucrose
Casein hydrolisate
Sorbitol
Dipotassium phosphate
Potassium dihydrogen phosphate
Phenol red
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the frozen virus suspension, as packaged for sale: 2 years.
Shelf life of the solvent, as packaged for sale: 30 months.

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

6.4 Special precautions for storage

Frozen virussuspension:
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.

6.5 Nature and composition of immediate packaging

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

Solvent:
Polyvinylchloride bag containing 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml or 1600 ml in individual over-pouch.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not re-use opened containers of diluted vaccine.

7 MARKETING AUTHORISATION HOLDER

CEVA-Phylaxia Veterinary Biologicals Co. Ltd
1107 Budapest
Szállás u. 5.
Hungary

8 MARKETING AUTHORISATION NUMBER(S)

VPA10463/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2 December 2016
Date of last renewal: 15 October 2021

10 DATE OF REVISION OF THE TEXT

October 2021

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of Cevac MD HVT may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Cevac MD HVT must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.