1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD Rispens concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose contains:

Active substance:
Cell-associated live Marek's disease virus (MDV)
serotype 1, strain CVI-988 800-5000 PFU*
*PFU: plaque forming unit

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
EMEM
L-glutamine
Sodium bicarbonate
Hepes
Bovine serum
Dimethyl sulfoxide
Water for injections
Solvent:
Sucrose
Casein hydrolysate
Sorbitol
Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Phenol red
Water for injections

Concentrate: yellow to reddish brown, dense, frozen virus suspension.
Solvent: clear, orange to red solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For active immunisation of one-day-old future layer chicks to reduce mortality, clinical signs and lesions caused by very virulent strains of Marek's disease virus.

Onset of immunity: 9 days after vaccination.
Duration of immunity: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease virus.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Spread of the vaccine strain was demonstrated between chickens and may occur from 14 days after vaccination. Vaccinated chickens may excrete the vaccine strain for at least 112 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.
The excreted vaccine strain is safe in non-vaccinated chickens.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species. Special precautions should be taken to avoid spreading of the vaccine strain to quails and pheasants.

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds: Do not use in birds in lay.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Vectormune ND by subcutaneous application.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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.

3.9 Administration routes and dosage

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. Overview table for recommended dilution possibilities of different presentations:

Cevac MD Rispens No. of ampoules x doses (D)	**Solvent presentation (ml)**	**Volume of one dose (ml)**
1 x 1,000 D	200	0.20
1 x 2,000 D	400	
2 x 2,000 D	800	
1 x 4,000 D	800	
4000 + 1000 D	1000	
3 x 2000 D	1200	
2 x 4000 D	1600	

Overview table for recommended dilution possibilities of different presentations in case of associated use:

No. of ampoules x doses (D)		**Solvent presentation (ml)**	**Volume of one dose (ml)**
Cevac MD Rispens	**Vectormune ND**		
1 x 1,000 D	1 x 1,000 D	200	0.20
1 x 2,000 D	1 x 2,000 D	400	
2 x 2,000 D	2 x 2,000 D	800	
1 x 4,000 D	1 x 4,000 D	800	
4000 + 1000 D	4000 + 1000 D	1000	
3 x 2000 D	3 x 2000 D	1200	
2 x 4000 D	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. Use Cevac Solvent Poultry for reconstitution. 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.
In case of associated use different syringe should be used for each vaccine.
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 during vaccination session.

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances. Do not re-use opened containers of diluted vaccine.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD03

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Vectormune ND (where it is marketed) and solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product 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.

5.3 Special precautions for storage

Concentrate:
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.

5.4 Nature and composition of immediate packaging

Concentrate:
One Type I glass ampoule containing 1000, 2000 or 4000 doses.
The ampoules are put on canes with tag showing the number 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.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CEVA-Phylaxia Veterinary Biologicals Co. Ltd.

7. MARKETING AUTHORISATION NUMBER (S)

VPA10463/007/001

8. DATE OF FIRST AUTHORISATION

25/08/2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

06/05/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).