MIMIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac MD Rispens

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

MDV

3. BATCH NUMBER

Lot {number}
(*on the tag as well*)

1000 D
2000D
4000D
(*on the tag*)

4. EXPIRY DATE

Exp {mm/yyyy}
Store: -196°C
Once reconstituted use within 2 hours

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING OF THE SOLVENT

Solvent bags of 200 ml, 400 ml, 800 ml, 1000 ml, 1200 ml, 1600 ml

1. NAME OF THE DILUENT/SOLVENT

Cevac Solvent Poultry

2. TARGET SPECIES

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. EXPIRY DATE

Exp. {month/year}

5. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.
Do not freeze.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo or Ceva Animal Health Ltd

7. BATCH NUMBER

Lot {number}

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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

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

3. Target species

Chickens

4. Indications for use

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.

5. Contraindications

None

6. Special warnings

Vaccinate only healthy animals.

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.

Laying birds: Do not use in birds in lay

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.

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

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

7. Adverse events

Chickens: none known.
Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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	

9. Advice on correct administration

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:

- 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.
- 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.
- Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39°C.
- 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.
- Once the ampoule is open, slowly draw up the content into the 5-ml sterile syringe prepared as in point 2.
-

- Transfer the thawed suspension into the solvent bag. The reconstituted vaccine prepared as described is mixed by gentle agitation.
- 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.
- 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.
Do not use Cevac MD Rispens 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 periods

Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/4151

Pack sizes
Concentrate:
One Type I glass ampoule containing 1000, 2000 or 4000 doses.
The ampoules are put on canes with tag and stored in a liquid nitrogen container.

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel. 01628 334056
email technicalandpvuk-group@ceva.com

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

17. Other information

POM-V

Gavin Hall
Approved: 18 August 2025