

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Ampoules of 1,000, 2,000 or 4,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune ND

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

rHVT/ND

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

1,000 doses
2,000 doses
4,000 doses

4. ROUTE(S) OF ADMINISTRATION

SC or in-ovo use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

PARTICULARS TO APPEAR ON THE IMMEDIATE OR OUTER PACKAGES

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Solvent Poultry

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

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

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

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

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

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Company logo

or

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/5030

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vectormune ND 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:

CEVA-Phylaxia Co. Ltd.
1107 Budapest
Szállás u. 5.
HUNGARY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune ND suspension and solvent for suspension for injection for chickens

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

Cell-associated live recombinant viral turkey herpes virus (rHVT/ND) expressing the fusion protein of Newcastle disease virus D-26 lentogenic strain: 2,500–8,000 PFU*/dose

* PFU: plaque forming units

Orange-yellowish semi-transparent frozen suspension.
The solvent is a clear red solution.

4. INDICATION(S)

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

Onset of immunity against Newcastle disease for broilers and layers: 3 weeks of age.
Duration of immunity against Newcastle disease for broilers: 9 weeks of age.
Duration of immunity against Newcastle disease for layers: 18 weeks of age.

Onset of immunity against Marek's disease for broilers and layers: 1 week of age.
Duration of immunity for broilers and layers: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease virus.

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.

7. TARGET SPECIES

Chickens and embryonated chicken eggs.

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

In-ovo administration:

One single injection of 0.05 ml is applied to each 18-day-old embryonated broiler chicken egg. For in-ovo application an automatic in-ovo egg injector can be used.

Subcutaneous use:

One single injection of 0.2 ml per chick is applied for broilers or layers at one day of age. The vaccine may be applied by an automatic syringe.

Overview table for dilution possibilities of different presentations:

For in-ovo administration:

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
2 x 2,000	200	0.05
1 x 4,000	200	0.05
2 x 4,000	400	0.05
4 x 4,000	800	0.05
5 x 4,000	1000	0.05
6 x 4,000	1200	0.05
8 x 4,000	1600	0.05

The speed of automatic injection is at least 2,500 eggs per hour, therefore solvent presentation of at least or more than 400 ml is recommended to prime and inject for longer than 10 minutes. In-ovo equipment should be calibrated to ensure that a 0.05 ml dose is applied to each egg.

Solvent presentation smaller than 400 ml is not recommended to be used for in-ovo application as it may not be enough to prime the machine and to inject longer than 10 minutes. The 200 ml presentation may be used for manual vaccination.

For subcutaneous use:

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
1 x 1,000	200	0.20
1 x 2,000	400	0.20
2 x 2,000	800	0.20
1 x 4,000	800	0.20
4,000 + 1,000	1000	0.20
3 x 2,000	1200	0.20
2 x 4,000	1600	0.20

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.

Procedure for preparing vaccine suspension:

1. After matching the dose size of the vaccine ampoule presentation with the solvent bag 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.
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's 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 already containing 2 ml solvent with a needle of at least 18 gauge diameter.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat it one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2 to 7 for the appropriate number of ampoules to be thawed.

Use the 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 vaccine suspension is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine suspension remains homogeneous and that the correct vaccine virus titre is administered (e.g. when automatic in-ovo injection machines are used or during long vaccination sessions).

After adding the content of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Do not use Vectormune ND 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.

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.

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. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

Vaccinated chicks may excrete the vaccine strain. There was a slow spread to turkeys which was not detectable at 35 days but was detectable after 42 days of a contact study. Special precautions should be taken to avoid spreading of the vaccine strain to turkeys.

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 only by properly trained personnel.

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.

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:

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Cevac Transmune by in ovo or subcutaneous vaccination for broilers. The mixed products protect against Newcastle disease virus, virulent Marek's disease virus and very virulent avian Infectious Bursal Disease (IBD) viruses. The safety and efficacy of the mixed vaccines are not different from those described for the vaccines administered separately. Read also the product information of Cevac Transmune before use.

In-ovo administration:

One single dose of 0.05 ml is injected into each 18-day-old embryonated broiler chicken egg.

Match the dose size of the vaccines and the sterile solvent according to the table below.

Vectormune ND	Cevac Transmune	Sterile solvent
2 x 2,000 doses	2 x 2,000 doses	200 ml
1 x 4,000 doses	1 x 4,000 doses	200 ml
2 x 4,000 doses	2 x 4,000 doses	400 ml
4 x 4,000 doses	4 x 4,000 doses	800 ml
5 x 4,000 doses	5 x 4,000 doses	1000 ml
6 x 4,000 doses	6 x 4,000 doses	1200 ml
8 x 4,000 doses	8 x 4,000 doses	1600 ml

Subcutaneous use:

One single injection of 0.2 ml per chick is applied for broilers at one day of age.

Match the dose size of the vaccines and the sterile solvent according to the table below.

Vectormune ND	Cevac Transmune	Sterile solvent
2 x 1,000 doses	1 x 2,000 doses	400 ml
1 x 2,000 doses	1 x 2,000 doses	400 ml
2 x 2,000 doses	2 x 2,000 doses	800 ml
1 x 4,000 doses	1 x 4,000 doses	800 ml
4,000 + 1,000 doses	4,000 + 1,000 doses	1000 ml
3 x 2,000 doses	3 x 2,000 doses	1200 ml
2 x 4,000 doses	2 x 4,000 doses	1600 ml

Draw up 2 ml of sterile solvent into a 5 ml syringe then draw up the thawed content of Vectormune ND ampoule in it.

Draw up 2 ml of sterile solvent into another 5 ml syringe then dissolve the content of Cevac Transmune vial in it.

Transfer the dissolved vaccines into the solvent bag and mix by gentle agitation.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Cevac MD Rispens by subcutaneous application. Read also the product information of Cevac MD Rispens before use.

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	

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product, except Cevac Transmune and Cevac MD Rispens (where it is marketed). 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.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except Cevac Transmune and Cevac MD Rispens (where it is marketed) and the solvent (Cevac Solvent Poultry) supplied for use with the veterinary medicinal 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

April 2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

Marketing authorisation numbers: 15052/5030

One glass ampoule of 1,000; 2,000 or 4,000 doses of the vaccine. Ampoules are put on cane, supplied with a tag showing the dose.

The canes with ampoules are stored in a liquid nitrogen container.

Polyvinylchloride bag containing 200 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 400 ml of solvent in individual over-pouch.

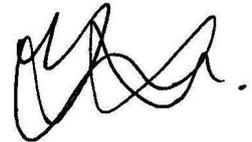
Polyvinylchloride bag containing 800 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 1000 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 1200 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 1600 ml of solvent in individual over-pouch.

Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 14 April 2023