ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune ND suspension and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine (0.05 ml in ovo administration or 0.2 ml subcutaneous use) contains:

Active substance:

Turkey herpesvirus, strain rHVT/ND (cell-associated) expressing fusion protein gene of Newcastle disease virus (strain D-26), live 2,500 – 8,000 PFU*

* PFU: plaque forming units.

Excipients:

Qualitative composition of excipients and other constituents
Suspension:
Eagle's minimum essential medium
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

Suspension: orange-yellowish semi-transparent frozen suspension.
Solvent: clear red solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and embryonated chicken eggs.

3.2 Indications for use for each target species

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.

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:

The vaccine strain was shown to be excreted by chickens and there was a slow spread to turkeys which was not detectable at 35 days but was detectable after 42 days of a contact study. Safety trials show the excreted vaccine strain is not harmful in turkeys; however, special precautions should be taken to avoid spreading of the vaccine strain to turkeys.

No spread was demonstrated between chickens.

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 homogenous and that the correct vaccine virus titre is administered (e.g. when automatic in-ovo injection machines are used or during long vaccination sessions).

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 general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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 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 and within 4 weeks before the start of the laying period.

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 Cevac Transmune by in ovo or subcutaneous vaccination. 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 vaccine 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.

3.9 Administration routes and dosage

For in ovo administration and subcutaneous use.

In ovo administration:
One single dose of 0.05 ml is injected into each 18-day-old embryonated broiler 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.

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 presentations smaller than 400 ml are not recommended to be used for in ovo application by an automated machine as it may not be enough to prime the machine and to inject for longer than 10 minutes. The 200 ml presentation may be used for manual vaccination.

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 injected by an automatic syringe.

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

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.

Preparation of vaccine suspension for injection:

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 of 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 the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat 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.
After adding the content of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

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 dose 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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release is required for this product

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD

The efficacy of the vaccine was proven by challenges with the virulent Marek's disease virus strain MD70 and with the NDV strain Herts 33/56.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Suspension: 3 years
Solvent: 30 months

Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Suspension:
One type I glass ampoule containing 1,000, 2,000 or 4,000 doses of the vaccine. Ampoules are put on a cane, supplied with a tag showing the dose.
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 Co. Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/188/004-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/09/2015

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

DD/MM/YYYY

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*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

rHVT/ND

1,000 doses
2,000 doses
4,000 doses
(The numbers of doses are only printed on tags on the canes used for storage of the ampoules in liquid nitrogen).

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT (EMA/CMDv/244519/2021 – Rev. 1)

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

1. NAME OF THE SOLVENT

Cevac Solvent Poultry

2. PACKAGE SIZE

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

3. TARGET SPECIES

Read the package leaflet before use.

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. EXPIRY DATE

Exp. {mm/yyyy}

6. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Do not freeze.

7. NAME OF THE MARKETING AUTHORISATION HOLDER

Company logo
or
CEVA-Phylaxia Co. Ltd.

8. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vectormune ND suspension and solvent for suspension for injection

2. Composition

Each dose of reconstituted vaccine (0.05 ml in ovo administration or 0.2 ml subcutaneous use) contains:

Turkey herpesvirus, strain rHVT/ND (cell-associated) expressing fusion protein gene of Newcastle disease virus (strain D-26), live 2,500 – 8,000 PFU*

* PFU: plaque forming units

Suspension: orange-yellowish semi-transparent frozen suspension.
Solvent: clear red solution.

3. Target species

Chickens and embryonated chicken eggs.

4. Indications for use

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. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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.

~~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 homogenous and that the correct vaccine virus titre is administered (e.g. when automatic in ovo injection machines are used or during long vaccination sessions).~~

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 general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently 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.

Overdose:

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

Major 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.

Special restrictions for use and special conditions for use:

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release is required for this product

7. Adverse events

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: {national system details}

8. Dosage for each species, routes 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.

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.

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:

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 discolouration 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.

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

Shelf life after reconstitution according to directions: 2 hours

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/15/188/004-006

Suspension:
One glass ampoule of 1,000; 2,000 or 4,000 doses of the vaccine. Ampoules are put on a cane, supplied with a tag showing the dose.
The canes with ampoules are stored in a liquid nitrogen container.

Solvent:
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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary
Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51