SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune ND suspension and solvent for suspension for injection for chickens

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:

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

* PFU: plaque forming units.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection.
Orange-yellowish semi-transparent frozen suspension.
The solvent is a clear 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 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.

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 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 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

Laying birds:
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 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
5x4000 doses	5x4000 doses	1000 ml
6x4000 doses	6x4000 doses	1200 ml
8x4000 doses	8x4000 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
4000 + 1000 doses	4000 + 1000 doses	1000 ml
3 x 2000 doses	3 x 2000 doses	1200 ml
2 x 4000 doses	2 x 4000 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.

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

4.9 Amounts to be administered and administration route

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.

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.

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 4000	1000	0.05
6 x 4000	1200	0.05
8 x 4000	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 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.

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
4000 + 1000	1000	0.20
3 x 2000	1200	0.20
2 x 4000	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.

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. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, live viral vaccines for domestic fowls.
ATCvet code: QI01AD.

The efficacy of the vaccine was challenged with the virulent Marek's disease virus strain MD70.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Suspension:
EMEM
L-glutamine
Sodium bicarbonate
Hepes
Bovine serum
Dimethyl sulfoxide
Water for injection

Solvent:
Sucrose
Casein hydrolysate
Sorbitol
Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Phenol red
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:

Suspension: 2 years
Solvent: 30 months
Shelf life after reconstitution according to directions: 2 hours.

6.4 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.

6.5 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 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

7. MARKETING AUTHORISATION HOLDER

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HP10 0HH
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5030

9. DATE OF FIRST AUTHORISATION

8 September 2015

10. DATE OF REVISION OF THE TEXT

October 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, 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.

Approved 21 October 2022