ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEWFLEND ND H9 concentrate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml or 0.2 ml) contains:

Active substance:

Turkey herpesvirus, strain rHVT/ND/H9 (cell-associated), expressing fusion protein gene of Newcastle disease virus and hemagglutinin gene of Avian influenza virus subtype H9, Live:
3 000 – 12 000 PFU*

*plaque forming unit

Excipient:

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

Concentrate: yellowish brown concentrate.
Solvent: clear, orange to red solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and embryonated chicken eggs.

3.2 Indications for use for each target species

For the active immunisation of one-day-old chicks or 18day-old chicken embryonated eggs:

- to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV),
- to reduce clinical signs, lesions and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9)

Onset of immunity:

NDV:	3 weeks of age (reduction of virus shedding has been demonstrated from 4 weeks of age)
LPAIV-H9:	4 weeks of age

Duration of immunity:

NDV:	until 9 weeks after vaccination
LPAIV-H9:	until 9 weeks after vaccination

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:

Vaccinate all the chickens in a flock at the same time.

The vaccine strain was shown to be excreted by chickens and there was a slow spread to turkeys which was only detectable after 49 days of contact with vaccinated chickens.

Safety trials have shown that the excreted vaccine strain is not harmful in turkeys. However, appropriate veterinary and husbandry measures such as cleaning and disinfection procedures should be taken to avoid spread of the vaccine strain to turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Liquid nitrogen containers and vaccine should be handled by properly trained personnel only.

Personal protective equipment consisting of protective gloves, face shield or goggles and boots should be worn when handling the veterinary medicinal product, i.e. before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.

Frozen glass ampoules can explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the vapour of liquid nitrogen is dangerous.

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

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

In ovo and subcutaneous use.

In ovo administration: one dose of 0.05 ml to be administered to 18-day-old chicken embryonated eggs.
Subcutaneous use: one dose of 0.2 ml to be administered to one-day-old chicken in the back of the neck.

Preparation of vaccine:

Use sterile devices and equipment for reconstitution and for administration of the vaccine. Before withdrawing concentrate from liquid nitrogen container, protect hands with gloves and use goggles and boots. When removing an ampoule from the strip, hold palm of gloved hand away from body and face.

1. After matching the dose size of the concentrate with the solvent size, quickly remove from liquid nitrogen container the exact number of ampoules needed.
2. Draw up 2 to 5 ml of solvent into a 5 to 10 ml sterile syringe. Use at least 18-gauge needles.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39 °C. Discard any ampoules that have been accidentally thawed and do not re-freeze them under any circumstances.
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 syringe already containing 2 to 5 ml solvent.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation. Do not re-use opened containers of diluted vaccine.
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. The ready to use veterinary medicinal product is a clear, homogeneous, red coloured suspension for injection. Regularly agitate the diluted vaccine throughout the vaccination process by turning up and down several times to ensure homogeneity of the suspension.

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

Proposed dilutions for *in ovo* administration:

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

Number of concentrate vials	Solvent	Volume of one dose

4 x 2 000 doses	400 ml	0.05 ml
2 x 4 000 doses	400 ml	0.05 ml
4 x 4 000 doses	800 ml	0.05 ml
5 x 4 000 doses	1 000 ml	0.05 ml
6 x 4 000 doses	1 200 ml	0.05 ml
8 x 4 000 doses	1 600 ml	0.05 ml

Proposed dilutions for subcutaneous use:

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

Number of concentrate vials	Solvent	Volume of one dose
2 x 1 000 doses	400 ml	0.2 ml
1 x 2 000 doses	400 ml	0.2 ml
1 x 4 000 doses	800 ml	0.2 ml
3 x 2 000 doses	1 200 ml	0.2 ml
2 x 4 000 doses	1 600 ml	0.2 ml

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

No symptoms were observed after the administration of a 10-fold maximum 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 may be required for this product according to national requirements.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD

The vaccine contains a cell-associated, live recombinant herpesvirus of turkey (HVT, Marek's disease virus serotype 3) which is genetically modified to express the gene of NDV fusion (F) protein and the gene of the haemagglutinin protein (HA) of LPAIV. The vaccine induces active immunity against infection with NDV and against infection with LPAIV subtype H9.

As the vaccine strain includes only the gene coding for the haemagglutinin protein of avian influenza virus, it is possible to differentiate between vaccinated and infected birds using a diagnostic test to detect neuraminidase antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent (Cevac Solvent Poultry) supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product (concentrate) as packaged for sale: 3 years.
Shelf life of the solvent as packaged for sale: 30 months.
Shelf life after dilution according to directions: 2 hours.

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.

Solvent:

Store below 25 °C.

Do not freeze.

5.4 Nature and composition of immediate packaging

Concentrate:

2 ml hydrolytic type I glass ampoule, containing 1 000 2,000 or 4 000 doses.
The ampoules are put on canes with tag and stored in a liquid nitrogen container.

Solvent:

Plastic bags made of polyvinylchloride:400 ml, 800 ml, 1 000 ml, 1 200 ml and 1 600 ml.

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.

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/2/23/296/001
EU/2/23/296/002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 16/05/2023

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

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

Concentrate ampoules and tags of 1,000, 2,000 or 4,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEWFLEND ND H9

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

rHVT/ND/H9

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

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 400 ml, 800 ml, 1000 ml, 1200 ml or 1600 ml

1. NAME OF THE SOLVENT

Cevac Solvent Poultry

2. PACKAGE SIZE

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

NEWFLEND ND H9 concentrate and solvent for suspension for injection

2. Composition

Each dose (0.05 ml or 0.2 ml) contains:

Active substance:
Turkey herpesvirus, strain rHVT/ND/H9 (cell-associated), expressing fusion protein gene of Newcastle disease virus and hemagglutinin gene of Avian influenza virus subtype H9, Live:
3 000 – 12 000 PFU*

*plaque forming unit

Concentrate: yellowish brown concentrate.
Solvent: clear, orange to red solution.

3. Target species

Chickens and embryonated chicken eggs.

4. Indications for use

For the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs:

- to reduce clinical signs, lesions and virus shedding caused by Newcastle disease virus (NDV),
- to reduce clinical signs, lesions, and virus shedding caused by H9 subtype of low pathogenic avian influenza virus (LPAIV-H9)

Onset of immunity:

NDV:	3 weeks of age (reduction of virus shedding has been demonstrated from 4 weeks of age)
LPAIV-H9:	4 weeks of age

Duration of immunity:

NDV:	until 9 weeks after vaccination
LPAIV-H9:	until 9 weeks after vaccination

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Vaccinate all the chickens in a flock at the same time.
In order to prevent spread of vaccine strain from vaccinated chicken flocks to non-vaccinated flocks, appropriate veterinary and husbandry measures such as cleaning and disinfection procedures should be taken.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Liquid nitrogen containers and vaccine should be handled by properly trained personnel only.
Personal protective equipment consisting of protective gloves, face shield or goggles and boots should be worn when handling the veterinary medicinal product, i.e. before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.
Frozen glass ampoules can explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the vapour of liquid nitrogen is dangerous.

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

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 may be required for this product according to national requirements.
Major incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal 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 dose of 0.05 ml to be administered to 18-day-old chicken embryonated eggs.
Subcutaneous use: one dose of 0.2 ml to be administered to one day-old chicken.

Proposed dilutions for *in ovo* administration:

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

Number of concentrate vials	Solvent	Volume of one dose
4 x 2,000 doses	400 ml	0.05 ml
2 x 4,000 doses	400 ml	0.05 ml
4 x 4,000 doses	800 ml	0.05 ml
5 x 4,000 doses	1,000 ml	0.05 ml
6 x 4,000 doses	1,200 ml	0.05 ml
8 x 4,000 doses	1,600 ml	0.05 ml

Proposed dilutions for subcutaneous use:

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

Number of concentrate vials	Solvent	Volume of one dose
2 x 1,000 doses	400 ml	0.2 ml
1 x 2,000 doses	400 ml	0.2 ml
1 x 4,000 doses	800 ml	0.2 ml
3 x 2,000 doses	1,200 ml	0.2 ml
2 x 4,000 doses	1,600 ml	0.2 ml

9. Advice on correct administration

Preparation of vaccine suspension for injection:

1. After matching the dose size of the concentrate with the solvent size, quickly remove from liquid nitrogen container the exact number of ampoules needed.
2. Draw up 2 to 5 ml of solvent into a 5 to 10 ml sterile syringe. Use at least 18-gauge needles.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27-39 °C. Discard any ampoules that have been accidentally thawed and do not re-freeze them under any circumstances.
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 syringe already containing 2 to 5 ml solvent.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation. Do not re-use opened containers of diluted vaccine.
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. The ready to use veterinary medicinal product is a clear, homogeneous, red coloured suspension for injection. Regularly agitate the diluted vaccine through vaccination process by turning up and down several times to ensure homogeneity of the suspension.

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Veterinary medicinal product (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.

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 after 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.

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

EU/2/23/296/001-003

Concentrate: 2 ml hydrolytic type I glass ampoule, containing 1 000 2,000 or 4 000 doses. The ampoules are put on canes with tag and stored in a liquid nitrogen container.

Solvent: Plastic bags made of polyvinylchloride: 400 ml, 800 ml, 1 000 ml, 1 200 ml and 1 600 ml.

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 events:

Ceva-Phylaxia Co. Ltd.

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