**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEWFLEND ND H9 concentrate and solvent for suspension for injection for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml or 0.2 ml) contains:

**Active substance:**
Cell-associated live recombinant turkey herpesvirus (rHVT/ND/H9), expressing the fusion protein of Newcastle disease virus and the hemagglutinin of low pathogenic avian influenza virus, subtype H9:
3,000 - 12,000 PFU*
*plaque forming unit

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection
Concentrate: yellowish brown concentrate.
Solvent: clear, orange to red solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chickens and chicken embryonated eggs.

### 4.2 Indications for use, specifying the target species

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 |

### 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

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.

## 4.6 Adverse reactions (frequency and seriousness)

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

## 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

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.

## 4.9 Amounts to be administered and administration route

*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 |

### 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 fowl.
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 fusion (F) gene of NDV and 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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

### 6.2 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.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product (concentrate) as packaged for sale: 24 months
Shelf life of the solvent as packaged for sale: 30 months
Shelf life after dilution according to directions: 2 hours.

### 6.4. 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.

### 6.5 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.

### 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

Ceva-Phylaxia Co. Ltd.
1107 Budapest
Szállás u. 5.
Hungary

## 8. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/296/001
EU/2/23/296/002
EU/2/23/296/003

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 May 2023

## 10 DATE OF REVISION OF THE TEXT

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

## 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.
The use of this veterinary medicinal product is only allowed under the particular conditions established by European Union legislation on the control of Avian Influenza.

## ANNEX II

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

**C. STATEMENT OF THE MRLs**

## A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Ceva-Phylaxia Co. Ltd.
1107 Budapest
Szállás u. 5.
Hungary

Name and address of the manufacturer responsible for batch release

Ceva-Phylaxia Co. Ltd.
1107 Budapest
Szállás u. 5.
Hungary

## B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Union legislation on the control of Avian Influenza.
The holder of this marketing authorisation must inform the European Commission about the marketing plans for the veterinary medicinal product authorised by this decision.

Official control authority batch release is required for this product.

## C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Concentrate ampoules of 1,000, 2,000 or 4,000 doses**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEWFLEND ND H9

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

rHVT/ND/H9

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

1,000 doses
2,000 doses
4,000 doses
*(in the tag only)*

## 4. ROUTE(S) OF ADMINISTRATION

*In ovo* / SC

## 5. WITHDRAWAL PERIOD(S)

## 6. BATCH NUMBER

Lot
*(also in the tag)*

## 7. EXPIRY DATE

EXP

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Cane with tag**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

**3. EXPIRY DATE**

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

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

**4. BATCH NUMBER**

Lot

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Solvent bags of 400 ml, 800 ml, 1,000 ml, 1,200 ml, 1,600 ml**

## 1. NAME OF THE DILUENT

Cevac Solvent Poultry

## 2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

400 ml
800 ml
1,000 ml
1,200 ml
1,600 ml

## 3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 4. STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

## 5. BATCH NUMBER

Lot

## 6. EXPIRY DATE

EXP

## 7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**

**NEWFLEND ND H9 concentrate 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

NEWFLEND ND H9 concentrate and solvent for suspension for injection for chickens

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

Each dose (0.05 ml or 0.2 ml) contains:

**Active substance:**
Cell associated live recombinant rHVT/ND/H9 3,000- 12,000 PFU*
*plaque forming unit

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

## 4. INDICATION(S)

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. ADVERSE REACTIONS

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

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 chicken embryonated eggs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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, 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 PERIOD(S)

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.

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:
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.

Lay:

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 (symptoms, emergency procedures, antidotes):
No symptoms were observed after the administration of a 10-fold dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

Veterinary medicinal product (concentrate): 2 ml hydrolytic type I glass ampoule, containing 1,000, 2,000 or 4,000 doses.

Solvent (Cevac Solvent Poultry): 400 ml, 800 ml, 1,000 ml, 1,200 ml and 1,600 ml in plastic bag made of polyvinylchloride.

Not all pack sizes may be marketed.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Union legislation on the control of Avian Influenza.