ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-ILT concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
Cell-associated live recombinant turkey herpesvirus (strain HVT/NDV/ILT), expressing the fusion protein of Newcastle disease virus and the glycoproteins gD and gI of infectious laryngotracheitis virus: $10^{3.3}$ – $10^{4.3}$ PFU*.

*PFU – plaque forming units.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection.
Cell concentrate: off-red to red cell concentrate.
Solvent: 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 one-day-old chicks or 18-19 day-old embryonated chicken eggs:
- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.

Onset of immunity: ND: 5 weeks of age,
ILT: 4 weeks of age
MD: 9 days.

Duration of immunity: ND: 62 weeks,
ILT: 62 weeks,
MD: entire risk period.

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
As this is a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The handling of liquid nitrogen should take place in a well-ventilated area.
Innovax-ND-ILT is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn.
In case of an accident to prevent serious wounds by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold palm of gloved hand away from body and face.
Care should be exercised to prevent contaminating your hands, eyes and clothing with the ampoule content. CAUTION: Ampoules have been known to explode on sudden temperature changes. Do not thaw in hot or ice-cold water. For this reason, thaw the ampoules in clean water at 25–27 °C.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that the vaccine can be mixed in the same solvent and administered by the subcutaneous route with Nobilis Rismavac. For this mixed use, an onset of immunity of 5 days has been demonstrated for MD.

Safety and efficacy data are available which demonstrate that Nobilis ND Clone 30 or Nobilis ND C2 can be administered in day-old chicks vaccinated either by the subcutaneous or in ovo route with the vaccine. For this associated use an onset of immunity of 2 weeks has been demonstrated for ND.
Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 or Nobilis IB 4-91 can be administered in day-old chicks vaccinated either by the subcutaneous or in ovo route with the vaccine.

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

Subcutaneous and in ovo use.

Preparation of the vaccine:
The usual aseptic precautions should be applied to all preparation and administration procedures. The handling of liquid nitrogen should take place in a well-ventilated area.

1. Use solvent for cell associated poultry vaccines for reconstitution. Reconstitute the vaccine according to the tables below:

   For subcutaneous use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for subcutaneous use
Bag of 400 ml solvent	1 ampoule containing 2000 doses
Bag of 800 ml solvent	2 ampoules containing 2000 doses
Bag of 800 ml solvent	1 ampoule containing 4000 doses

For *in ovo* use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for *in ovo* use
Bag of 400 ml solvent	4 ampoules containing 2000 doses
Bag of 400 ml solvent	2 ampoules containing 4000 doses
Bag of 800 ml solvent	8 ampoules containing 2000 doses
Bag of 800 ml solvent	4 ampoules containing 4000 doses

The solvent must be clear, red coloured, without sediment and at room temperature (15–25 °C) at the time of mixing.

2. Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane, so special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct solvent is used.
3. Before withdrawing the ampoules from the liquid nitrogen container, protect hands with gloves, wear long sleeves and use a facemask or goggles. When removing an ampoule from the cane, hold in the palm of a gloved hand away from the body and the face.
4. When withdrawing a cane of ampoules from the canister in the liquid nitrogen container, expose only the ampoule(s) to be used immediately. It is recommended to handle a maximum of 5 ampoules (from one cane only) at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.
5. The content of the ampoule(s) is thawed rapidly by immersing in clean water at 25–27 °C. Gently swirl the ampoule(s) to disperse the contents. It is important that the ampoule content, after being thawed, is mixed immediately into the solvent to protect the cells.
   Dry the ampoule, then break the ampoule at its neck and immediately proceed as described below.
6. Gently withdraw the contents of the ampoule into a sterile syringe, mounted with an 18 gauge needle.
7. Insert the needle through the stopper of the solvent bag and add slowly and gently the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a portion of the solvent into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
8. The vaccine is now ready for use.
   After adding the content of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Posology:
Subcutaneous: One single injection of 0.2 ml per chick.
In ovo: One single injection of 0.05 ml per egg.

Administration:
The vaccine is administered by subcutaneous injection in the neck or by *in ovo* injection. The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered (e.g. during long vaccination sessions).

Control of correct storage:
To allow a check on correct storage and transport the ampoules are placed upside down in the liquid nitrogen containers. If frozen content is situated in the tip of the ampoule this indicates that the content has been thawed and must not be used.

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: QI01AD17.

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus and the gD and gI glycoproteins of infectious laryngotracheitis virus. The vaccine induces active immunity against Newcastle disease, infectious laryngotracheitis and Marek's disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cell concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide

Solvent:
Sucrose
Pancreatic digest of casein
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the medicinal product or Nobilis Rismavac.

6.3 Shelf life

Shelf life of the cell concentrate as packaged for sale: 3 years.
Shelf life of the solvent as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4. Special precautions for storage

Cell concentrate:
Store and transport frozen in liquid nitrogen (below -140 °C).
Solvent:
Store below 25 °C.
Container:
Store liquid nitrogen container securely in upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

6.5 Nature and composition of immediate packaging

Cell concentrate:
- Type I glass ampoule of 2 ml containing 2,000 or 4,000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2,000 doses: salmon-pink coloured clip, and 4,000 doses: yellow coloured clip).

Solvent:
- 400 ml multilayer plastic bag.
- 800 ml multilayer plastic bag.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/256/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16/09/2020

10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

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.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES 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 manufacturers of the biological active substance

Intervet International B.V.
Ambachtstraat 2-6
3732 CN De Bilt
THE NETHERLANDS

Intervet Inc.
29160 Intervet Lane
PO Box 318, Millsboro
Delaware 19966-0318
UNITED STATES OF AMERICA

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

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.

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 either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

Official control authority batch release is required for this product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE 2000/4000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-ILT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

HVT/NDV/ILT

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

2,000
4,000
(number of doses per ampoule is presented on the colour coded clip attached to each cane containing the ampoule)

4. ROUTE(S) OF ADMINISTRATION

SC
In ovo

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
<please note; the sentence 'for animal treatment only' will only appear in English and will not be translated>

MSD Animal Health Logo

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SOLVENT BAG 400/800 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for cell associated poultry vaccines

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

400 ml
800 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot

6. EXPIRY DATE

EXP

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Innovax-ND-ILT 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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-ILT concentrate and solvent for suspension for injection for chickens

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

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

Cell-associated live recombinant turkey herpesvirus (strain HVT/NDV/ILT), expressing the fusion protein of Newcastle disease virus and the glycoproteins gD and gI of infectious laryngotracheitis virus: $10^{3.3}$ – $10^{4.3}$ PFU*.

*PFU – plaque forming units.

Concentrate and solvent for suspension for injection.
Cell concentrate: off-red to red cell concentrate.
Solvent: clear, red solution.

4. INDICATION(S)

For active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs:
- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.

Onset of immunity: ND: 5 weeks of age,
ILT: 4 weeks of age
MD: 9 days.

Duration of immunity: ND: 62 weeks,
ILT: 62 weeks,
MD: entire risk period.

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

After dilution, administer one dose of 0.2 ml vaccine per chicken by subcutaneous injection in the neck or one dose of 0.05 ml per egg by *in ovo* injection.

9. ADVICE ON CORRECT ADMINISTRATION

The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered (e.g. during long vaccination sessions).

Preparation of the vaccine:
The usual aseptic precautions should be applied to all preparation and administration procedures. The handling of liquid nitrogen should take place in a well-ventilated area.

1. Use solvent for cell associated poultry vaccines for reconstitution. Reconstitute the vaccine according to the tables below:

   For subcutaneous use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for subcutaneous use
Bag of 400 ml solvent	1 ampoule containing 2000 doses
Bag of 800 ml solvent	2 ampoules containing 2000 doses
Bag of 800 ml solvent	1 ampoule containing 4000 doses

   For *in ovo* use reconstitute the vaccine according to the table below:

Solvent bag	Number of vaccine ampoules for *in ovo* use
Bag of 400 ml solvent	4 ampoules containing 2000 doses
Bag of 400 ml solvent	2 ampoules containing 4000 doses
Bag of 800 ml solvent	8 ampoules containing 2000 doses
Bag of 800 ml solvent	4 ampoules containing 4000 doses

   The solvent must be clear, red coloured, without sediment and at room temperature (15–25 °C) at the time of mixing.
2. Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane, so special care has to be taken to ensure that the mix-ups of ampoules with different number of doses is avoided and the correct solvent is used.
3. Before withdrawing the ampoules from the liquid nitrogen container, protect hands with gloves, wear long sleeves and use a facemask or goggles. When removing an ampoule from the cane, hold in the palm of a gloved hand away from the body and the face.
4. When withdrawing a cane of ampoules from the canister in the liquid nitrogen container, expose only the ampoule(s) to be used immediately. It is recommended to handle a maximum of 5

ampoules (from one cane only) at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.

5. The content of the ampoule(s) is thawed rapidly by immersing in clean water at 25–27 °C. Gently swirl the ampoule(s) to disperse the contents. It is important that the ampoule content, after being thawed, is mixed immediately into the solvent to protect the cells.
   Dry the ampoule, then break the ampoule at its neck and immediately proceed as described below.
6. Gently withdraw the contents of the ampoule into a sterile syringe, mounted with an 18 gauge needle.
7. Insert the needle through the stopper of the solvent bag and add slowly and gently the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a portion of the solvent into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
8. The vaccine is now ready for use.
   After adding the content of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

Control of correct storage:
To allow a check on correct storage and transport the ampoules are placed upside down in the liquid nitrogen containers. If frozen content is situated in the tip of the ampoule this indicates that the content has been thawed and must not be used.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Cell concentrate: Store and transport frozen in liquid nitrogen (below –140 °C).
Solvent: Store below 25 °C.
Container: Store liquid nitrogen container securely in upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

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:
As this is a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The handling of liquid nitrogen should take place in a well-ventilated area.
Innovax-ND-ILT is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, protective equipment consisting of gloves,

long sleeves and a facemask or goggles should be worn. In case of an accident to prevent serious wounds by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold palm of gloved hand away from body and face. Care should be exercised to prevent contaminating your hands, eyes and clothing with the ampoule content. CAUTION: Ampoules have been known to explode on sudden temperature changes. Do not thaw in hot or ice-cold water. For this reason, thaw the ampoules in clean water at 25–27 °C.

Lay:
The safety of the veterinary medicinal product has not been established during lay.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that the vaccine can be mixed in the same solvent and administered by the subcutaneous route with Nobilis Rismavac. For this mixed use, an onset of immunity of 5 days has been demonstrated for MD.

Safety and efficacy data are available which demonstrate that Nobilis ND Clone 30 or Nobilis ND C2 can be administered in day-old chicks vaccinated either by the subcutaneous or *in ovo* route with the vaccine. For this associated use an onset of immunity of 2 weeks has been demonstrated for ND.

Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 or Nobilis IB 4-91 can be administered in day-old chicks vaccinated either by the subcutaneous or *in ovo* route with the vaccine.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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 or Nobilis Rismavac.

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

Medicines should not be disposed of via wastewater or household waste.
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

{DD/MM/YYYY}

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

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus and the gD and gI glycoproteins of infectious laryngotracheitis virus. The

vaccine induces active immunity against Newcastle disease, infectious laryngotracheitis and Marek's disease in chickens.

Pack sizes:
1 ampoule containing 2,000 or 4,000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2,000 doses: salmon-pink coloured clip, and 4,000 doses: yellow coloured clip).

Bag of 400 ml solvent or bag of 800 ml solvent.

Not all pack sizes may be marketed.