ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-H5 concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
Turkey herpesvirus, strain HVT-ND-H5 (cell-associated), expressing fusion protein gene of Newcastle disease virus and haemagglutinin gene of avian influenza virus subtype H5: $10^{3.3}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide
Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

Concentrate: off-red to red cell concentrate.
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 one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic Avian Influenza (HPAI) virus of the H5 type.

Onset of immunity: 2 weeks

Duration of immunity: 12 weeks (reduction of mortality and clinical signs demonstrated with *in ovo* administration)

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

MDA (against H5) can interfere with efficacy of the vaccine.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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-H5 is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, personal protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn when handling the veterinary medicinal product. In order to prevent serious wounds, by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold the palm of the (gloved) hand holding the ampoule away from the body and face. Care should be exercised to prevent contaminating the hands, eyes and clothing with the ampoule content.

CAUTION: The ampoules have been known to explode on exposure to sudden temperature changes. Do not thaw in hot water or ice-cold water. Thaw the ampoules in clean water at 25 °C – 27 °C.

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 the respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Safety data are available which demonstrate that Innovax-ND-H5 can be mixed in the same solvent and administered by the subcutaneous use with Nobilis Rismavac.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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, taken into consideration the information in section 4.1.

3.9 Administration routes and dosage

Posology:
Subcutaneous use: one single injection of 0.2 ml per chick.
In ovo: one single injection of 0.05 ml per chicken egg.

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.

   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
Bag of 1200 ml solvent	3 ampoules containing 2000 doses
Bag of 1600 ml solvent	4 ampoules containing 2000 doses
Bag of 1600 ml solvent	2 ampoules containing 4000 doses

   When this product is mixed with Nobilis Rismavac, both should be diluted in the same solvent bag in the same way (400 ml of solvent for each 2000 doses of both products or 800 ml of solvent for each 4000 doses of both products).

   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
Bag of 1200 ml solvent	12 ampoules containing 2000 doses
Bag of 1200 ml solvent	6 ampoules containing 4000 doses
Bag of 1600 ml solvent	16 ampoules containing 2000 doses
Bag of 1600 ml solvent	8 ampoules containing 4000 doses

   The solvent must be clear, red coloured, without sediment and at room temperature (15 °C – 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 the 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. Thaw the content of the ampoule(s) rapidly by immersing the ampoule in clean water at 25 °C – 27 °C. Gently swirl the ampoule(s) to disperse the contents. In order to protect the cells, it is important that the ampoule content is mixed, immediately after thawing, with the solvent. 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 fitted with an 18-gauge needle.
7. Insert the needle through the stopper of the solvent bag, and then slowly and gently add the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a small quantity from the solvent bag into the syringe and rinse the ampoule. Inject the remaining contents of the ampoule gently into the solvent bag.
8. Repeat steps 6 and 7 for additional ampoules, if required.
9. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
10. The vaccine is now ready for use.
    After adding the contents of the ampoule to the solvent, the ready to use product is a clear, red coloured suspension for injection.

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.

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 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 is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus (NDV) and the haemagglutinin antigen of avian influenza virus (AIV) of the H5 subtype. The vaccine induces active immunity against Marek's disease, Newcastle disease and avian influenza virus of the H5 subtype in chickens. Antibodies against MDV, NDV and AIV can therefore be detected after vaccination.

The vaccine strain contains the gene that encodes the hemagglutinin protein of avian influenza virus, it is therefore possible to distinguish between vaccinated and infected birds through a commercially available diagnostic test that detects antibodies against the nucleoprotein.

Challenge strain of the circulating clade 2.3.4.4.b has been used in the efficacy studies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the concentrate as packaged for sale: 3 years.
Shelf life of the solvent (multilayer plastic bags) as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Concentrate:
Store and transport frozen in liquid nitrogen (below -140 °C).

Solvent:
Store below 30 °C.

Container:
Store liquid nitrogen container securely in an upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room.

5.4 Nature and composition of immediate packaging

Concentrate:
- One Type I glass ampoule of 2 ml containing 2000 or 4000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2000 doses: salmon-pink coloured clip, and 4000 doses: yellow coloured clip).

Solvent:
- One 400 ml multilayer plastic bag.
- One 800 ml multilayer plastic bag.
- One 1200 ml multilayer plastic bag.
- One 1600 ml multilayer plastic bag.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/315/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 22/05/2024.

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

{MM/YYYY}

EXCEPTIONAL CIRCUMSTANCES:
Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

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

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

This being an approval under exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

Description	**Due date**
Combined identity/potency test. The following information should be provided: • Monoclonal mouse-antibodies for AIV-H5 and NDV-F respectively are used for the immunofluorescence staining. A precise description and protocol for the preparation of the monoclonal antibodies is lacking (AIV-H5 MoAb and NDV-F MoAb). • Potency: An internal reference standard is used as positive control in the potency test. More detailed information should be provided from which batch the internal standard originates and how it was qualified. It should be also detailed how the titre specifications were established.	July 2024
CEF cells. CEF cells could be either provided by a supplier or alternatively obtained prepared in- house. Two CoA from two different suppliers are attached for CEF cells as well as for the embryonated chicken eggs: • The applicant should indicate whether the full set of extraneous agents testing is performed for all CEF cells. The list of extraneous agents tested by one of the suppliers does not mention testing for Atadenovirus (Avian Adenovirus Serogroup 3), which is required according to Ph. Eur. 5.2.2. However, in the document "Extraneous agents risk assessment in the final product," the applicant states that the SPF eggs are tested for Altadenovirus. In the CoA from another supplier, no details regarding extraneous agents testing are mentioned. Therefore, the applicant is requested to clearly indicate whether the same extraneous agents testing procedures are performed irrespective of the source of embryonated SPF eggs or CEF cells. • The applicant should confirm that all bovine sera and trypsin used for cell cultivation in all sites are appropriately tested for extraneous agents. • It should be confirmed whether the extraneous agents testing programs for all eggs/CEF cells from all possible suppliers are in line with the requirements of Ph. Eur. 5.2.2. • The applicant is asked to further elaborate how absence of *Chlamydia* spp. In the CEF preparations is guaranteed.	July 2024
Stability data. The results of real time stability studies for the vaccine, up to 39 months, should be provided to confirm the 3 years shelf-life claim. Any out of specification detected should be communicated immediately to the European Medicines Agency.	June 2026

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE (GLASS, 2 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-H5

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

HVT-ND-H5

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SOLVENT BAG 400/800/1200/1600 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
1200 ml
1600 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 30 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {MM/YYYY}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Innovax-ND-H5 concentrate and solvent for suspension for injection for chickens

2. Composition

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

Active substance:
Turkey herpesvirus, strain HVT-ND-H5 (cell-associated), expressing fusion protein gene of Newcastle disease virus and haemagglutinin gene of avian influenza virus subtype H5: $10^{3.3}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

Concentrate: off-red to red cell concentrate.
Solvent: clear, red solution.

3. Target species

Chickens and embryonated chicken eggs.

4. Indications for use

For active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic Avian Influenza (HPAI) virus of the H5 type.

Onset of immunity: 2 weeks
Duration of immunity: 12 weeks (reduction of mortality and clinical signs demonstrated with *in ovo* administration)

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

MDA (against H5) can interfere with efficacy of the vaccine.

Special precautions for safe use in the target species:
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-H5 is a virus suspension packed in glass ampoules and stored in liquid nitrogen. Before withdrawing ampoules from the liquid nitrogen canister, personal protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn when handling the veterinary medicinal product. In order to prevent serious wounds, by either the liquid nitrogen or the ampoules when removing an ampoule from the canister, hold the palm of the (gloved) hand holding the ampoule away from the body and face. Care should be exercised to prevent contaminating the hands, eyes and clothing with the ampoule content. CAUTION: The ampoules have been known to explode on exposure to sudden temperature changes. Do not thaw in hot water or ice-cold water. Thaw the ampoules in clean water at 25 °C – 27 °C.

Special precautions for the protection of the environment:
Not applicable.

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

Interaction with other medicinal products and other forms of interaction:
Safety data are available which demonstrate that Innovax-ND-H5 can be mixed in the same solvent and administered by the subcutaneous use with Nobilis Rismavac.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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, taken into consideration the information in "Other information" section.

Overdose:
No symptoms were observed after the administration of a 10-fold 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except Nobilis Rismavac and 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

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.
   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
Bag of 1200 ml solvent	3 ampoules containing 2000 doses
Bag of 1600 ml solvent	4 ampoules containing 2000 doses
Bag of 1600 ml solvent	2 ampoules containing 4000 doses

   When this product is mixed with Nobilis Rismavac, both should be diluted in the same solvent bag in the same way (400 ml of solvent for each 2000 doses of both products or 800 ml of solvent for each 4000 doses of both products).

   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
Bag of 1200 ml solvent	12 ampoules containing 2000 doses
Bag of 1200 ml solvent	6 ampoules containing 4000 doses
Bag of 1600 ml solvent	16 ampoules containing 2000 doses
Bag of 1600 ml solvent	8 ampoules containing 4000 doses

   The solvent must be clear, red coloured, without sediment and at room temperature (15 °C – 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 the 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. Thaw the content of the ampoule(s) rapidly by immersing the ampoule in clean water at 25 °C – 27 °C. Gently swirl the ampoule(s) to disperse the contents. In order to protect the cells, it is important that the ampoule content is mixed, immediately after thawing, with the solvent. 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 fitted with an 18-gauge needle.
7. Insert the needle through the stopper of the solvent bag, and then slowly and gently add the contents of the syringe to the solvent. Gently swirl and invert the bag to mix the vaccine. Withdraw a small quantity from the solvent bag into the syringe and rinse the ampoule. Inject the remaining contents of the ampoule gently into the solvent bag.
8. Repeat steps 6 and 7 for additional ampoules, if required.
9. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
10. The vaccine is now ready for use.
    After adding the contents 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 periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Concentrate: Store and transport frozen in liquid nitrogen (below –140 °C).
Solvent: Store below 30 °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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/315/001-002

Pack sizes:
1 ampoule containing 2000 or 4000 doses. Ampoules are stored on a cane and attached to the cane is a coloured clip displaying the dose (2000 doses: salmon-pink coloured clip, and 4000 doses: yellow coloured clip).

Bag of 400 ml solvent, bag of 800 ml solvent, bag of 1200 ml solvent or bag of 1600 ml solvent.

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:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: +420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: +30 210 989 7452

Latvija
Tel: + 37052196111

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: +420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus (NDV) and the haemagglutinin antigen of avian influenza virus (AIV) of the H5 subtype. The vaccine induces active immunity against Marek's disease, Newcastle disease and avian influenza virus of the H5 subtype in chickens. Antibodies against MDV, NDV and AIV can therefore be detected after vaccination.

The vaccine strain contains the gene that encodes the hemagglutinin protein of avian influenza virus, it is therefore possible to distinguish between vaccinated and infected birds through a commercially available diagnostic test that detects antibodies against the nucleoprotein.

Challenge strain of the circulating clade 2.3.4.4.b has been used in the efficacy studies.