ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE 2000/4000 doses (2 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-ILT

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

HVT/NDV/ILT

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE SOLVENT

SOLVENT BAG 400/800/1200/1600 ml

1. NAME OF THE DILUENT/SOLVENT

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. ROUTES 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

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: 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 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. SPECIAL WARNING(S)

Special warnings:
Vaccinate healthy animals only.

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

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

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:
UK(GB) and **UK(NI)**: Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
IE: HPRA Pharmacovigilance; Website: www.hpra.ie

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
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 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°C –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.
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 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.

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.

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

Vm 01708/5041

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

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. 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.

POM-V Veterinary medicinal product subject to prescription

For animal treatment only.

Approved 28 April 2024