PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT
SOLVENT BAG 400/800/1,200/1,600 ml

1. NAME OF THE DILUENT/SOLVENT

Solvent for cell associated poultry vaccines

2. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

Exp. {month/year}

4. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

5. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health logo

6. BATCH NUMBER

Lot {number}

The following additional text appears on the label. This allows UK(GB) to make use of the multi-country multi-lingual solvent label approved for use with the Innovax range of products:

For animal treatment only.

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

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 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 lesions caused by Marek's disease (MD) virus.
- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,
- 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: MD – 5 days; ND – 4 weeks; HPAI H5 – 2 weeks.
Duration of immunity: MD is lifelong, ND and HPAI – 12 weeks.
For HPAI: duration of immunity (reduction of mortality and clinical signs demonstrated) with in ovo administration.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Maternally derived antibodies (against HPAI H5 virus) 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 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, 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 competent authority on the current vaccination policies, as these activities may be prohibited in 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 for cell associated poultry vaccines 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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. Reconstitute the vaccine according to the tables below:

Solvent bag	Number of vaccine ampoules for subcutaneous use
Bag of 400 ml solvent	1 ampoule containing 2,000 doses
Bag of 800 ml solvent	2 ampoules containing 2,000 doses
Bag of 800 ml solvent	1 ampoule containing 4,000 doses
Bag of 1,200 ml solvent	3 ampoules containing 2,000 doses
Bag of 1,600 ml solvent	4 ampoules containing 2,000 doses
Bag of 1,600 ml solvent	2 ampoules containing 4,000 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 2,000 doses
Bag of 400 ml solvent	2 ampoules containing 4,000 doses
Bag of 800 ml solvent	8 ampoules containing 2,000 doses
Bag of 800 ml solvent	4 ampoules containing 4,000 doses
Bag of 1,200 ml solvent	12 ampoules containing 2,000 doses
Bag of 1,200 ml solvent	6 ampoules containing 4,000 doses
Bag of 1,600 ml solvent	16 ampoules containing 2,000 doses
Bag of 1,600 ml solvent	8 ampoules containing 4,000 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.

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 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 01708/5131

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, bag of 800 ml solvent, bag of 1,200 ml solvent or bag of 1,600 ml solvent.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

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

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 Limited.
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 (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.

POM-V

Gavin Hall

Approved: 26 June 2025