SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ND-IBD 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:
Cell-associated live recombinant turkey herpesvirus (strain HVP360), expressing the fusion protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus: $10^{3.3}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection.
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 prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus,
- to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus.

Onset of immunity: ND: 4 weeks of age
IBD: 3 weeks of age
MD: 9 days

Duration of immunity: ND: 60 weeks
IBD: 60 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-IBD 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 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.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 section “Contact details” of the package leaflet.

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 Innovax-ND-IBD 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 or Nobilis IB Ma5 or Nobilis IB 4-91 can be administered (not mixed) to day-old chicks that are vaccinated either by the subcutaneous or by the in ovo route with Innovax-ND-IBD. For such associated use, an onset of immunity of 3 weeks (when used with Nobilis ND Clone 30) and 2 weeks (when used with Nobilis ND C2), has been demonstrated for ND.

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 Amount(s) to be administered and administration route

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.
6. Dry the ampoule, then break the ampoule at its neck and immediately proceed as described below.
7. Gently withdraw the contents of the ampoule into a sterile syringe fitted with an 18-gauge needle.
8. 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.
9. Repeat steps 6 and 7 for additional ampoules, if required.
10. Remove the syringe and invert the bag (6–8 times) to mix the vaccine.
11. The vaccine is now ready for use.
12. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms were observed after the administration of a 10-fold dose of vaccine when applied subcutaneously. A 3-fold overdose was tested *in ovo*, which was regarded as safe. No information is available on the safety or possible adverse reactions following a 10-fold overdose applied *in ovo*.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, live viral vaccines for domestic fowls.

ATCvet code: QI01AD16.

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the F protein of Newcastle disease virus and the VP2 protein of infectious bursal disease virus. The vaccine induces active immunity against Newcastle disease, infectious bursal disease (Gumboro disease) and Marek's disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Concentrate
Bovine serum
Veggie medium
Dimethyl sulfoxide

Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

6.2 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.

6.3 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.

6.4 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.

6.5 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.

6.6 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.

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5040

9. DATE OF FIRST AUTHORISATION

22 August 2017

10. DATE OF REVISION OF THE TEXT

July 2023

PROHIBITION OF SALE, SUPPLY AND/OR 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 a country on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved 07 February 2024