

# Cell Associated Live Recombinant Herpes virus of Turkey strain HVP360

371843 R6

Innovax™-ND-IBD

**NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY**

Warning: To be sold by retail on the prescription of a "Veterinary Doctor" only.

**Description**

Innovax-ND-IBD is a frozen, cell associated, live virus vaccine that contains the recombinant serotype 3 HVT with genes from NDV and IBDV. The vaccine can be used to stimulate active immunity against MD, ND and IBD.

**Active substance (s)**

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<sub>1</sub>.

1 PFU – plaque forming units.

**Target species**

Chickens and embryonated chicken eggs.

**Pharmaceutical Form**

Suspension and solvent for suspension for injection.

Suspension: off red to red suspension

Solvent: clear, red solution

**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 prevent mortality and to reduce clinical signs and lesions caused by Infectious Bursal Disease (IBD) virus,
- to prevent mortality and to reduce clinical signs and lesions caused by Marek's Disease (MD) virus.

**Immunity**

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

Duration of immunity: ND: 8 weeks,  
IBD: 8 weeks,  
MD: entire risk period.

**Contraindication**

None.

**Special warning for the Target Species**

Vaccinate healthy birds only

**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 suspension. 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 25–27 °C.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

**Adverse reactions (frequency and seriousness)**

None known.

**Use during pregnancy, lactation or 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 Nobilis ND Clone 30 or Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or 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.

Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 or Nobilis IB 4-91 can be administered to day-old chicks that are 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.

**Amounts to be administered and administration route**

Subcutaneous use 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.

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 subcutaneous 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 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 25–27 °C. Gently swirl the ampoule(s) to disperse the contents. In order to protect the cells, it is important that the suspension 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. 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 contents 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 chicken 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 suspension is situated in the tip of the ampoule this indicates that the suspension has been thawed and must not be used.

#### List of excipients

Suspension:

Bovine serum

Veggie medium

Dimethyl sulfoxide

Solvent:

Sucrose

Pancreatic digest of casein

Phenolsulfonphthalein (Phenol red)

Potassium dihydrogen phosphate

Water for injections

#### Incompatibilities

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

#### Shelf life

Shelf life of the cell suspension as packaged for sale: 2 years.

Shelf life of the solvent (polyethylene bags) as packaged for sale: 3 years.

Shelf life of the solvent (multilayer plastic bags) as packaged for sale: 2 years.

Shelf life after reconstitution according to directions: 2 hours.

#### Special precautions for storage

Cell suspension:

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.

#### Nature and composition of immediate packaging

Suspension:

- Type I glass ampoules 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 polyethylene or multilayer plastic bags of solvent.

- 800 ml polyethylene or multilayer plastic bags of solvent.

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

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

#### Withdrawal period(s)

Zero days.

#### Immunological properties

Pharmacotherapeutic group: immunologicals for Aves, live viral vaccines for domestic fowls.

ATCvet code: QI01AD.

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 and Marek's disease in chickens.

#### Manufactured by

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#### Imported & Marketed by

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