SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 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 HVT/IBD/ILT), expressing the VP2 protein of infectious bursal disease virus and the glycoproteins gD and gI of infectious laryngotracheitis virus: $10^{3.2}$ – $10^{4.6}$ PFU[1].

[1] PFU – plaque forming units.

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 (one day-old chicks and embryonated eggs).

4.2 Indications for use, specifying the target species

For active immunisation of one-day-old chicks or 18-19 day-old embryonated eggs:
- to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.
- to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus.

Onset of immunity: IBD: 3 weeks of age,
ILT: 4 weeks of age,
MD: 5 days of age.

Duration of immunity: IBD: 100 weeks,
ILT: 100 weeks,
MD: entire risk period.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Chickens with maternally derived antibodies, when vaccinated with this veterinary medicinal product, may have a delayed onset of immunity against IBD.

4.5 Special precautions for use

Special precautions for use in animals

As 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-ILT-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 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.

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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

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 the vaccine Innovax-ILT-IBD can be mixed in the same solvent and administered by either *in ovo* or subcutaneous route with Nobilis Rismavac.

Safety and efficacy data are available which demonstrate that this vaccine can be administered to one-day-old chicks on the same day but not mixed with Nobilis ND Clone 30 or Nobilis ND C2 or Nobilis IB Ma5 or Nobilis IB 4-91. For such associated uses, an onset of immunity of 3 weeks has been demonstrated for ND and IB.

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

Subcutaneous use or *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. 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**
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	3 ampoules containing 2,000 doses
Bag of 1,600 ml	4 ampoules containing 2,000 doses
Bag of 1,600 ml	2 ampoules containing 4,000 doses

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	12 ampoules containing 2,000 doses
Bag of 1,200 ml	6 ampoules containing 4,000 doses
Bag of 1,600 ml	16 ampoules containing 2,000 doses
Bag of 1,600 ml	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 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.

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 2,000 doses of both products or 800 ml of solvent for each 4,000 doses of both products).

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI01AD18.

The vaccine is a cell-associated live recombinant turkey herpesvirus (HVT) expressing the VP2 protein of infectious bursal disease virus and the gD and gI glycoproteins of infectious laryngotracheitis virus. The vaccine induces active immunity against infectious bursal disease (Gumboro disease), infectious laryngotracheitis 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 the solvent supplied for use with the veterinary medicinal product or Nobilis Rismavac.

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 upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room in the hatchery.

6.5 Nature and composition of immediate packaging

Concentrate:
- Type I glass ampoule of 2 ml 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:
- One 400 ml multilayer plastic bag.
- One 800 ml multilayer plastic bag.
- One 1,200 ml multilayer plastic bag.
- One 1,600 ml multilayer plastic bag.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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/ 5082

9. DATE OF FIRST AUTHORISATION

26 March 2024

10. DATE OF REVISION OF THE TEXT

March 2024

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.

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

Approved 26 March 2024