INNOVAX™-ILT-IBD

Intervet/Merck Animal Health

DIRECTIONS FOR USE, READ CAREFULLY

BURSAL DISEASE-INFECTIOUS LARYNGOTRACHEITIS-MAREK'S DISEASE-NEWCASTLE DISEASE VACCINE,

Serotype 3, Live Marek's Disease Vector

Frozen

For *In ovo* Vaccination of 18-19-Day-Old Embryonated Chicken Eggs and Subcutaneous Vaccination of Day Old Chickens

DESCRIPTION

This vaccine is a frozen, cell associated, live virus vaccine that contains the recombinant serotype 3 turkey herpesvirus with genes from infectious laryngotracheitis virus and with the VP2 gene from infectious bursal disease virus. The vaccine is packaged in glass ampules and supplied with diluent packaged in a separate container. The vaccine ampules are inserted in metal canes, stored and shipped in a liquid nitrogen container.

INDICATIONS FOR USE

This product has been shown to be effective for the vaccination of healthy 18-19 day-old embryonated chicken eggs, or one-day-old chickens, against Marek's disease, infectious laryngotracheitis and standard infectious bursal disease. Duration of immunity has not been established. For more information regarding efficacy and safety data, see productdata.aphis.usda.gov.

Inject 0.2 mL per chick for the subcutaneous route or 0.05 - 0.1 mL per embryonated chicken egg for the *in ovo* route.

IMPORTANT: STORAGE CONDITIONS

AMPULES: Store in liquid nitrogen container.

DILUENT: Do not freeze.

CONTAINER: Store liquid nitrogen container securely in upright position in a dry, well ventilated area and away from incubator intakes and chicken boxes.

SAFETY PRECAUTIONS

Liquid nitrogen container and vaccine should be handled only by properly trained personnel regarding the use of, precautions and safe practices for liquefied atmospheric gases (particularly liquid nitrogen). When removing ampule cane,

handling frozen ampules, or adding liquid nitrogen, wear long sleeves, a plastic face shield and gloves to protect the skin from contact with the liquid nitrogen. All storage and handling of the liquid nitrogen container must be in a dry, ventilated area. Do not inhale liquid nitrogen vapors. If drowsiness occurs, get fresh air quickly; then ventilate entire area. If breathing difficulty occurs, apply artificial respiration. If any of these difficulties persist or there is a loss of consciousness, summon a physician immediately. Care should be exercised to prevent contaminating your hands, eyes and clothing with the vaccine.

PREPARATION OF VACCINE

CAUTION: READ ABOVE SAFETY PRECAUTIONS ON HANDLING VACCINE AMPULE. AMPULES HAVE BEEN KNOWN TO EXPLODE ON SUDDEN TEMPERATURE CHANGES. DO NOT THAW IN HOT OR ICE COLD WATER.

1. Before withdrawing vaccine from liquid nitrogen canister, protect hands with gloves, wear long sleeves and use a facemask or goggles. It is possible an accident could occur with either the liquid nitrogen or the ampules of vaccine. When removing an ampule from the cane, hold palm of gloved hand away from body and face.

2. When withdrawing a cane of ampules from canister in liquid nitrogen container, expose only the ampules to be used immediately. We recommend handling a maximum of 4 ampules at a time. The remaining ampules should be replaced immediately in the canister of the liquid nitrogen container.

3. The contents of the ampule are thawed rapidly by immersing in a container of clean water at a temperature range of 20-30°C (68-86°F). Once the vaccine has thawed remove ampule from water bath. Gently swirl the ampule to disperse contents. Then break ampule at its neck and immediately proceed as below.

4. Dilute the vaccine for administration. Use 100 ml sterile diluent for each 1,000 doses of vaccine to administer 0.1 ml dose per embryonated chicken egg or use 50 ml for each 1,000 doses of vaccine to administer 0.05 ml per embryonated chicken egg by the *in ovo* route. Use 200 ml sterile diluent for each 1,000 doses of vaccine to administer 0.2 ml dose per chicken by the subcutaneous route.

5. Draw contents of ampule into a sterile 10 ml syringe, mounted with an 18 gauge needle.

6. Dilute immediately by filling the syringe slowly with a portion of the diluent. **IMPORTANT:** THE DILUENT SHOULD BE AT ROOM TEMPERATURE 16-27°C (60-80°F) AT TIME OF MIXING.

7. Slowly empty the syringe into the prepared diluent bag. Withdraw a portion of the diluent with the syringe to rinse ampule. Remove the remaining diluent from the ampule and inject gently into the diluent bag. Mix gently.

8. Fill the previously sterilized automatic syringe or egg inoculation machine according to the manufacturer's recommendations.

9. The vaccine is now ready for use.

METHOD OF VACCINATION

1. For *in ovo* administration: inoculate each 18-19-day-old embryonated chicken egg with a full dose (0.05 ml or 0.1 ml). For subcutaneous administration: inoculate each day-old chicken with a full dose (0.2 ml).

2. Use entire contents of diluent bag within 1 hour after mixing.

3. After reconstitution, the vaccine should be kept cool and gently agitated frequently.

CAUTION

1. VACCINATE ONLY HEALTHY CHICKENS AND EMBRYONATED CHICKEN EGGS.

2. Do not mix with other products, except as specified on the label.

3. Store vaccine in liquid nitrogen at a temperature below -150°C (-238°F).

4. ONCE THAWED, THE PRODUCT SHOULD NOT BE REFROZEN.

5. Do not vaccinate within 21 days before slaughter.

6. Contains gentamicin as a preservative.

7. Inactivate unused contents before disposal.

8. In case of human exposure, contact a physician.

9. FOR ANIMAL USE ONLY.

NOTICE

This vaccine has undergone rigid potency, safety and purity tests, and meets Merck Animal Health., U.S. and local regulatory requirements. It is designed to stimulate effective immunity when used as directed, but the user must be advised that the response to the product depends upon many factors, including, but not limited to, conditions of storage and handling by the user, administration of the vaccine, health and responsiveness of the individual chickens, and the degree of field exposure.

RECORDS

Keep a record of vaccine, quantity, serial number, expiration date, and place of purchase; the date and time of vaccination; the number, age, breed, and locations of chickens; names of operators performing the vaccination and any observed reactions.

Intervet Inc., Omaha, NE 68103 USA

VLN 165A/PCN 1J81.R0

1 800 211-3573 (USA)

1 866 683-7838 (Canada)

393447 R4, 355954 R3

Presentation: 2,000 doses and 4,000 doses.

CPN: 1047587.0

ANNEX I

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.

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Bovine serum
Veggie medium
Dimethyl sulfoxide
Solvent:
Sucrose
Sodium chloride
Disodium hydrogen phosphate dihydrate
Phenolsulfonphthalein (Phenol red)
Potassium dihydrogen phosphate
Water for injections

Concentrate: off-red to red cell concentrate.
Solvent: clear, red solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and embryonated chicken eggs.

3.2 Indications for use for each target species

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 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

3.3 Contraindications

None.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

3.6 Adverse events

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 also section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

3.8 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.

3.9 Administration routes and dosage

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

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 can 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 2000 doses of both products or 800 ml of solvent for each 4000 doses of both products).

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 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.

5.3 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.

5.4 Nature and composition of immediate packaging

Concentrate:
- 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.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/292/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE 2000/4000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Innovax-ILT-IBD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

HVT/IBD/ILT

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SOLVENT BAG 400/800/1200/1600 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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. ROUTE(S) 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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Innovax-ILT-IBD 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/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.

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 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

5. Contraindications

None.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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.

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 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.

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 Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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: {national system details}.

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:

   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

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 can 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 2000 doses of both products or 800 ml of solvent for each 4000 doses of both products).

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 or household waste.

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 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

EU/2/23/292/001-002

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

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
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Nederland
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17. Other information

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