

INNOVAX®-ND-ILT

Infectious Laryngotracheitis - Marek's Disease - Newcastle Disease Vaccine

(Serotype 3, Live Marek's Disease Vector)

For *in ovo* vaccination of 18 day old chicken embryos and subcutaneous vaccination of day old chickens to provide protection against Newcastle disease (ND), infectious laryngotracheitis and Marek's disease.

ADVANTAGES:*

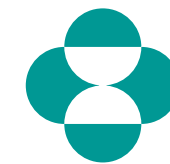
- Provides protection for virulent ND, ILT and Marek's disease.
- Offers effective protection in the face of ND virus maternal antibodies
- Replaces a conventional live ND vaccination program in the absence of exotic ND
- Removes the potential for respiratory reactions due to live ND and ILT vaccines
- No vaccine reactions observed in safety trials for improved bird performance
- Offers flexible administration via *in ovo* or subcutaneous injection to fit any vaccination schedule
- Eliminates an increase in vaccine reactions from other respiratory vaccines
- Eliminates latency, persistence, and spread caused by chickens vaccinated with live conventional ILT vaccines
- Prevents vaccine induced ILT outbreaks
- Allows the use of monovalent infectious bronchitis (IB) vaccines, improving IB protection



Innovax®-ND-ILT is a frozen, live, cell-associated ND, ILT and Marek's vaccine. It provides proven protection against virulent ND virus, ILT and Marek's. It is approved for *in ovo* injection of 18 day embryonated eggs and subcutaneous vaccination of day old chickens.

2,000 dose ampules

*Data on file, Merck Animal Health



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(Serotype 3, Live Marek's Disease Vector)



For *In ovo* Vaccination of 18 Day Old Chicken Embryos 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 the F gene from Newcastle disease virus and with genes from laryngotracheitis 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 day old chicken embryos or one day old chickens against Marek's disease, Newcastle disease and infectious laryngotracheitis. Duration of Immunity has not been established. For more information regarding efficacy and safety data, go to productdata.aphis.usda.gov.

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 who are thoroughly conversant with the Union Carbide publication and instruction booklet 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. STERILIZE VACCINATING EQUIPMENT BY BOILING IN WATER FOR 30 MINUTES OR BY AUTOCLAVING 20 MINUTES AT 121°C (250°F). DO NOT USE CHEMICAL DISINFECTANTS.

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 ampule to be used immediately. We recommend handling only one ampule at a time. After removing the ampule from the cane, 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). 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 chicken embryo or use 50 ml for each 1,000 doses of vaccine to administer 0.05 ml per chicken embryo 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. The contents of the filled syringe are then added to remaining diluent. It is important that this be done slowly. Slowly empty the syringe, allowing the vaccine to run down the side of the diluent container. Gently agitate the container as the vaccine is being mixed. Withdraw a portion of the diluent with the syringe to flush ampule. Remove the remaining diluent from the ampule and inject gently into the diluent container. Remove the syringe.
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

In ovo Administration:

1. Inoculate each 18 day old chicken embryo with a full dose (0.05 ml or 0.1ml).
2. Entire contents of container must be used within 1 hour after mixing or be discarded according to caution statement No. 11.
3. After reconstitution, the vaccine should be kept cool and gently agitated frequently.

Subcutaneous Administration:

1. Hold the chicken by the back of the neck just below the head. The loose skin in the area is raised by gently pinching with the thumb and forefinger. Insert the needle beneath the skin in a downward direction away from the head. Inject 0.2 ml per chicken.

2. Avoid hitting the muscles and bones in the neck.
3. Entire contents of container must be used within 1 hour after mixing or be discarded according to caution statement No. 11.

Notice

This vaccine has undergone rigid potency, safety and purity tests, and meets Intervet Inc., 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.

Caution

Good management practices are recommended to reduce exposure to Marek's disease and infectious laryngotracheitis for at least three weeks following vaccination. Therefore, directions should be followed carefully.

1. Do not mix any substance with this vaccine. Do not mix with other products, except as specified on this label.
2. Store vaccine in liquid nitrogen at a temperature below -150°C (-238°F).
3. Gloves and visor should be worn when handling liquid nitrogen.
4. ONCE THAWED, THE PRODUCT SHOULD NOT BE REFROZEN.
5. Do not dilute or otherwise stretch the dosage of this vaccine.
6. Once mixed with diluent, the vaccine should be gently agitated frequently.
7. Once mixed with diluent, the vaccine should be used within 1 hour.
8. Only healthy chicken embryos should be vaccinated.
9. Do not vaccinate within 21 days before slaughter.
10. This vaccine contains Gentamicin as a preservative.
11. Inactivate unused contents before disposal.
12. In case of human exposure, contact a physician.
13. FOR ANIMAL USE ONLY.

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.

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VLN/PCN 165A/1C91.R0

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