

INNOVAX[®]-ILT-IBD

Infectious Bursal Disease - Infectious Laryngotracheitis - Marek's Disease

(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 infectious bursal disease, infectious laryngotracheitis and Marek's disease.

ADVANTAGES:*

- Provides protection for virulent ILT, IBD and Marek's disease
- Unique dual glycoproteins (gD & gI) for enhanced ILT protection
- Removes the potential for respiratory reactions due to live ILT vaccines
- Eliminates an increase in vaccine reactions from other respiratory vaccines
- Eliminates latency, persistence, and spread caused by chickens vaccinated with live conventional 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
- Prevents vaccine induced ILT outbreaks

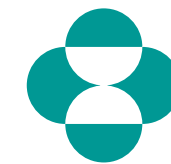


Innovax[®]-ILT-IBD is a frozen, live, cell-associated ILT, IBD and Marek's vaccine. It provides proven protection against ILT, IBD and Marek's disease. It is approved for *in ovo* injection of 18-day-old chicken embryos and subcutaneous vaccination of day-old chickens.

2,000 dose ampules

4,000 dose ampules

*Data on file, Merck Animal Health



MERCK
Animal Health



INNOVAX[®]-ILT-IBD

Infectious Bursal Disease - Infectious Laryngotracheitis - Marek's Disease

(Serotype 3, Live Marek's Disease Vector)



Frozen

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 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-day-old chicken embryos, 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.

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 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. 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-day-old chicken embryo with a full dose (0.05 ml or 0.1ml). 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 CHICKEN EMBRYOS.
2. Do not mix with other products, except as specified on this 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

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1 800 211-3573 (USA)

1 866 683-7838 (Canada)