PRODUCT BULLETIN

INNOVAX®-ILT-SB

Fowl Laryngotracheitis - Marek's Disease

(Serotypes 2 + 3, Modified-Live and Live Marek's Disease Vector)

For vaccination of 18 day old embryos to aid in the prevention of infectious laryngotracheitis (ILT) and very virulent Marek's disease (MD).

ADVANTAGES:*

- Provides extended protection against both ILT virus and very virulent MD
- Eliminates respiratory vaccination reactions caused by chickens vaccinated with live conventional ILT vaccines
- Eliminates an increase in the vaccination reactions from other respiratory vaccines
- Eliminates latency, persistence and spread caused by chickens vaccinated with live conventional ILT vaccines
- Prevents vaccine induced ILT outbreaks

Innovax®-ILT-SB vaccine is a frozen, live, cell-associated laryngotracheitis and MD vaccine. It provides proven protection against ILT and very virulent MD. It is approved for *in ovo* injection of 18 day embryonated eggs. Innovax-ILT-SB contains a turkey herpes virus (HVT) used as a vector for the expression of the glycoprotein genes from laryngotracheitis virus. The HVT is combined with the SB-1 strain of chicken herpes virus (serotype 2).

2,000 dose ampules

*Data on file, Merck Animal Health

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INNOVAX®-ILT-SB

Fowl Laryngotracheitis & Marek's Disease

(Serotypes 2 & 3, Modified-Live and Live Marek's Disease Vector)

For Animal Use Only.

Description

Innovax® -ILT-SB is a frozen, cell-associated, live virus vaccine that contains the SB-1 strain of chicken herpesvirus serotype 2 and the recombinant serotype 3 turkey herpesvirus 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

Innovax-ILT-SB is recommended for vaccination of healthy 18 day old chicken embryos by the *in ovo* route as an aid in the prevention of very virulent Marek's Disease and Infectious Laryngotracheitis.

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.

Vaccination Programs

Many factors must be considered in determining a sound vaccination program for a particular farm or poultry operation. To be fully effective, the vaccine must be administered to healthy, receptive birds held in proper environment under good management. In addition, the response may be modified by the age of the birds and their immune status. Seldom does 1 vaccination under field conditions produce complete protection for all individuals in a given flock. The amount of protection required will vary with the type of operation and the degree of exposure the flock is likely to encounter. For these reasons, a program of periodic revaccination may be required.

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 WARNING ADVICE ON HANDLING VACCINE AMPULE. AMPULES HAVE BEEN KNOWN TO EXPLODE ON SUDDEN TEMPERATURE CHANGES. DO NOT THAW IN HOT OR ICE COLD WATER. STERLIZE VACCINATING EQUIPMENT BY BOILING IN WATER FOR 30 MINUTES OR BY AUTOCLAVING (20 minutes at 250°F/121°C). DO NOT USE CHEMICAL DISINFECTANTS.

1. Before withdrawing vaccine from liquid nitrogen conister, protect hands with gloves, wear long sleeves and use a face mask 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, 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 68-86°F (20-30°C). 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 by the *in ovo* 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 (60-80°F/16-27°C) 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 containter. 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 Vaccination

IN OVO ADMINISTRATION

1. Inoculate each 18 day old chicken embryo with a full dose (0.05 ml or 0.1 ml).
2. Entire contents of container must be used within 1 hour after mixing or be discarded according to caution statement No. 7.
3. After reconstitution, the vaccine should be kept cool and gently agitated frequently.

Caution

READ FULL DIRECTIONS CAREFULLY.
GOOD MANAGEMENT PRACTICES ARE RECOMMENDED TO REDUCE EXPOSURE TO MAREK'S DISEASE AND INFECTIOUS LARYNGOTRACHEITIS FOR AT LEAST 3 WEEKS FOLLOWING VACCINATION. THEREFORE, DIRECTIONS SHOULD BE FOLLOWED CAREFULLY.

1. Do not mix any substance with this vaccine.
2. Store vaccine in liquid nitrogen at a temperature below -238°F (-150°C).
3. Gloves and visor should be worn when handling liquid nitrogen.
4. ONCE THAWED, THE PRODUCT SHOULD NOT BE REFROZEN.
5. Do not dilute the vaccine or otherwise stretch the dosage.
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. BURN THIS CONTAINER AND ALL UNUSED CONTENTS.

Notice

This product is not hazardous when used according to directions supplied. A safety data sheet (SDS) is available upon request. This and any other consumer information can be obtained by calling Merck Animal Health Customer Service at 1-800-211-3573.

Records

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

STORE VACCINE IN LIQUID NITROGEN.

Contact our sales or technical services representatives to help design a custom vaccination program.

MERCK Animal Health