

INTERVET/SCHERING-PLOUGH ANIMAL HEALTH (formerly Intervet Inc.)

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INNOVAX™-ILT

Intervet

FOWL LARYNGOTRACHEITIS - MAREK'S DISEASE VACCINE

Serotype 3, Live Marek's Disease Vector

Frozen

For Subcutaneous Vaccination of Day Old Chickens

READ IN FULL

DESCRIPTION

INNOVAX-ILT is a frozen, cell associated, live virus vaccine that contains the recombinant serotype 3 turkey herpesvirus with a gene 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 is recommended for vaccination of healthy one-day-old chickens by the subcutaneous route as an aid in the prevention of virulent Marek's Disease and Infectious Laryngotracheitis.

IMPORTANT: STORAGE CONDITIONS

AMPULES - Store in liquid nitrogen container.

DILUENT - Store at room temperature.

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 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. STERILIZE 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 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 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 using 200 ml diluent for each 1,000 doses of vaccine to administer 0.2 ml 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 (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 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 according to the manufacturer's recommendations.
9. The vaccine is now ready for use.

METHOD OF VACCINATION

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. and USDA 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.

This product is not hazardous when used according to directions supplied. A material safety data sheet (MSDS) is available upon request. This and any other consumer information can be obtained by calling Intervet Inc. Customer Service at 1-800-441-8272 or 1-302-934-8051.

CAUTION

Good management practices are recommended to reduce exposure to Marek's disease for at least three 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 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 chickens 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.**
12. **FOR VETERINARY 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.

HOW SUPPLIED

Sales Product Code	Packaging
006323	2,000 Dose Ampule 200 ml of Sterile Diluent per 1,000 Doses

The use of this vaccine is subject to applicable local and federal laws and regulations.

USE ONLY AS DIRECTED

STORE VACCINE IN LIQUID NITROGEN

THIS PRODUCT IS NON-RETURNABLE

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