

999483 R8



MSD
Animal Health



MAREK'S DISEASE-NEWCASTLE DISEASE VACCINE,

**Serotypes 2 & 3, Live Virus,
Live Marek's Disease Vector**

INNOVAX™-ND-SB

NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY

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 the SB-1 strain of chicken herpesvirus serotype 2. The vaccine is packaged in glass ampoules and supplied with diluent packaged in a separate container. The vaccine ampoules are inserted in metal canes, stored and shipped in a liquid nitrogen container.

COMPOSITION

Each ampoule contains per dose at least 1534 PFU per bird dose of Live Turkey Herpes Virus strain HVT/NDV-F and at least 1514 PFU per bird dose of Marek's disease Virus serotype 2 strain SB-1 in the cell associated form.

Excipients:

Bovine Serum.....5-30 %
Dimethyl sulfoxide..... 4-10 %
Gentamicin sulfate..... 0-0.05 mg/ml

INDICATIONS FOR USE

This vaccine is recommended for vaccination of healthy 18-day-old chicken embryos by the *in-ovo* route or day old chicks by subcutaneous route to aid in the prevention of very virulent Marek's disease and Newcastle disease.

IMPORTANT: STORAGE CONDITIONS

AMPOULES: Store in liquid nitrogen container.
DILUENT: Store at 15°C-25°C. 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 handling of liquid nitrogen. When removing ampoule cane, handling frozen ampoules, 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 AMPOULE. AMPOULES 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. Use **CA-Diluent** for reconstitution of the single or combined Cell-associated Marek vaccines. For subcutaneous injection, use 200 ml CA-diluent for each 1,000 doses of vaccine to inject 0.2 ml per chicken. For *in ovo* vaccination of eggs uses 500 ml CA diluent for each 10,000 doses of vaccine to inject 0.05 ml per egg.
The diluent must be clear, red-colored, without sediment and at room temperature (15-25°C) at the time of mixing.
2. Before withdrawing vaccine from the liquid nitrogen container, protect hands with gloves, wear long sleeves and use a facemask or goggles. When removing an ampoule from the strip, Hold palm of gloved hand away from body and face.
3. When withdrawing a strip of ampoules from the canister in the liquid nitrogen container, expose only the ampoules to be used immediately. We recommend handling only a maximum of 5 ampoules (one strip) at a time. After removing the ampoules, remaining ampoules should be placed immediately in the canister of the liquid nitrogen container.
4. The content of the ampoule(s) is thawed rapidly by immersing in clean water at 25-27°C. Gently swirl the ampoule to disperse contents. It is important that the vaccine after being thawed is mixed as soon as possible into the diluent to protect the cells.
Dry the ampoule, then break the ampoule at its neck and immediately proceed as below.

5. Gently draw the contents of the ampoule into a sterile syringe, with an 18-gauge needle.
6. Insert the needle through the stopper of the diluent bag and add slowly and gently the content of the syringe into the diluent. Gently swirl and invert the bag to mix the vaccine. Withdraw a portion of the diluent into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject gently into the diluent bag. Remove the syringe and invert the bag (6-8 times) to mix the vaccine.
7. 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).
2. After reconstitution, the vaccine should be kept cool and gently agitated frequently.

Day old subcutaneous Administration:

1. The vaccine is applied subcutaneously in the neck.
Inject 0.2 ml per chicken.
2. The bottle of vaccine must be swirled frequently. It should be stored in ice water if not used immediately.
3. Entire contents of bottle must be used within 2 hours after mixing. After that any remaining vaccine should be discarded.

WITHDRAWAL PERIOD

Zero days.

CONTRA-INDICATIONS

Do not vaccinate clinically ill or stressed birds.

SPECIAL WARNINGS

1. Do not mix any substance with this vaccine,
2. Burn the ampoules and all unused contents.
3. Keep vaccine ampoule frozen in liquid nitrogen until ready to vaccinate.
4. Do not use vaccine that has been thawed other than immediately before use. To allow a check on correct storage and transport the ampoules are placed upside down in the liquid nitrogen containers. If frozen vaccine is situated in the tip of the ampoule this indicates that the vaccine has been thawed and must not be used.
5. No information is available on the safety and efficacy from the concurrent use with other vaccines, except Intervet Nobilis ND C2, Nobilis ND Clone 30, or Bursal disease vaccine 89/03 and Innovax-ILT.

Do not use in conjunction with a vaccine containing a classical HVT strain or any other HVT recombinant vaccine other than Innovax-ILT.

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

1000 dose ampoule/ 2000 dose ampoule / 3,000 dose ampoule / 4,000 dose ampoule / 5,000 dose ampoule

**USE ONLY AS DIRECTED
STORE VACCINE IN LIQUID NITROGEN
THIS PRODUCT IS NON-RETURNABLE**

QUALITY tested for Purity, Potency and Safety

Manufactured by:

Intervet Inc.
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Imported and Marketed in India by:

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