

FOR ANIMAL TREATMENT ONLY

Vaxsafe[®] RIS Vaccine (living)

Active Constituent: Each dose contains ≥ 4000 pfu* Marek's disease virus (chicken herpesvirus serotype 1) Rispens strain CVI 988.

*plaque forming units

Statement of Claims: For the prevention of virulent Marek's disease in chickens.

The vaccine virus has been purified and grown in tissue cultures derived from specific pathogen free (SPF) eggs.

1000 / 2000 / 3000 / 4000 Doses

Contents: The product consists of one glass ampoule of vaccine and a plastic container of diluent. Each ampoule of vaccine contains a minimum of 1000 doses of vaccine. Ampoules containing 2000, 3000 and 4000 doses are on canes within cardboard sleeves; the sleeves being labelled with the number of doses per ampoule. Two hundred (200) mL of diluent is provided for each 1000 doses of vaccine. The glass ampoule is stored in liquid nitrogen [approx. -196°C]. The diluent is maintained at room temperature.

READ DIRECTIONS CAREFULLY

DIRECTIONS FOR USE:

Contraindications:

- This product is contraindicated for vaccinating unhealthy chickens.

Precautions:

- DO NOT place chickens in contaminated facilities or adjacent to older chickens.
- Exposure to wild-type Marek's disease virus must be minimised for at least 3 weeks after vaccination.
- Vaccinate all chickens on the premises at one time.
- Administer a full dose to each chicken.
- Avoid stressful conditions during and following vaccination.
- Use entire contents with 1 hr of preparation.
- Administer only as directed.
- Avoid carcass damage by carefully following instructions under 'Method of Vaccination'

Dosage and Administration:

The vaccine is for administration to day-old chickens by subcutaneous inoculation.

Preparation of vaccine for use:

Read the full instructions and follow them exactly.

- Know and follow all precautions and safety practices before handling liquid nitrogen.
- Before withdrawing ampoules from the liquid nitrogen vessel, protect hands with leather gloves, wear long sleeves and protect face and eyes with a plastic face shield or wear protective goggles. Ampoules that have been cracked during manufacture or transportation may explode.
- Vaccine ampoules are shipped in a vessel that has been pre-treated with liquid nitrogen. The transport vessel does NOT contain free liquid nitrogen, but holds the vaccine below -150°C . Vaccine must be removed from the transport vessel IMMEDIATELY upon arrival and into an on-site

storage vessel that contains liquid nitrogen. Vaccine transfer must be carried out as a direct transfer from the transport vessel into the on-site storage vessel. DO NOT EXPOSE VACCINE TO ROOM TEMPERATURE FOR MORE THAN 10 SEC. Each canister must be at -196°C AT THE TIME OF TRANSFER of the canes. If cardboard sleeves are present on the vaccine canes, they should be left in place until immediately prior to use. One cane per canister is shipped inverted. Vaccine in the tip of inverted ampoules may indicate thawing during transit. Contact BIOPROPERTIES IMMEDIATELY if this occurs.

- Mix vaccine in a well-ventilated clean room. Disinfect work station with alcohol prior to vaccine preparation. Prepare diluent pack by wiping the rubber stoppers with an alcohol swab. Match diluent pack with vaccine to be thawed at the rate of 200 mL per 1000 doses of vaccine. Diluent must be at room temperature ($22-25^{\circ}\text{C}$) at the time of use.
- Prepare syringe (10 mL) and needle (18 G x 37 mm) using aseptic technique. Add 3 mL of diluent to the syringe and replace cap.
- Remove from the liquid nitrogen only the ampoules that are going to be used immediately. (NOTE: remove ampoules in descending order from each cane; only raise the aluminium cane to the neck of the canister to ensure remaining ampoules are not exposed to room temperature). Ampoules removed from liquid nitrogen for more than 30 sec should not be returned to the liquid nitrogen container, as loss of titre will occur.
- Ampoules must be thawed QUICKLY (60-70 sec). Place no more than 2 ampoules in a large container containing 5-10 L of clean, freshly-prepared water. The water temperature must be maintained at $27-29^{\circ}\text{C}$ using a thermostatically controlled heating element and monitored using a certified thermometer. Remove gloves, collect the ampoules quickly and agitate gently during thawing to minimise thaw time. Avoid inverting ampoules which avoids vaccine entering lids. When the contents have thawed, remove ampoules from the thaw bath and wipe dry with clean paper towel. Remove the lids carefully within the towel by rotating the lids away from the operator. CAUTION: Fine glass pieces may be generated during lids removal so ensure eye protection is in place and ampoule lids are removed within the paper towel. The broken surface of lid and ampoule are sharp and should not be touched with fingers or paper to avoid cutting and contamination.
- Add approximately 1 mL of diluent to the open ampoule before inserting the needle to the bottom of the ampoule and SLOWLY withdrawing ampoule contents (Note: it is essential that the vaccine be withdrawn slowly from the ampoule to minimise damage to the delicate cells contained within the vaccine. Cell destruction reduces vaccine potency).
- SLOWLY expel contents into the diluent bottle through the rubber stopper of the diluent bag. Gently rock the bag during ejection. Withdraw a further 3 mL of diluent and gently rinse the inside of each ampoule from the top down. Eject the rinse back into the diluent bag slowly. Withdraw a further 1 mL of diluent into the syringe and eject immediately to rinse the syringe. Thoroughly mix the prepared vaccine by gently rocking the diluent bag back-and-forth at least 5-6 times.
- The vaccine may be used at room temperature or placed into an ice bath during use. Ensure all the vaccine is used within 1 hr after preparation. Agitate the vaccine every 10 min to ensure a uniform suspension of the cells.
- Use the vaccine/diluent mixture as described below.

Method of Vaccination:

- IMPORTANT: Sterilise vaccinating equipment by autoclaving for a minimum of 15 min at 121°C , or boiling in water for at least 20 min. NEVER allow chemical disinfectants to come in contact with vaccinating equipment.
- Give subcutaneously only.
- Vaccination may be undertaken with a hand-gun syringe or with an automatic vaccinator.
- A sterile automatic hand-gun syringe should be fitted with a 20 G x 25 mm needle that is set to accurately deliver 0.2

mL per dose. Check the accuracy of delivery several times during the vaccination procedure. Keep needles sharp and clean by replacing them frequently (approximately every 1000 chickens).

- Automatic vaccinators should be correctly disinfected, assembled and calibrated prior to the commencement of vaccine preparation. Pressure gauges, triggers, vaccine flow and operation should be monitored throughout vaccination.
- Maintain cleanliness at all times.
- Dilute the vaccine only as directed, observing all precautions and warnings for handling.
- Keep the bottle of diluted vaccine in an ice bath if the room temperature exceeds 27 °C and agitate frequently (every 10 min) during use.
- Inject chickens subcutaneously into the nape area (under the loose skin at the back of the neck) just below the head. The loose skin in this area is raised by gently pinching with the thumb and forefinger. Insert the needle beneath the skin in a direction away from the head. Inject 0.2 mL per chicken. Avoid hitting the muscles and bones in the neck.
- Maintain accuracy rather than speed. Staff using automatic syringes should not exceed 1500 chickens per hour. Staff using automatic vaccinators should not exceed 3000 chickens per hour otherwise chickens may be missed.
- Use the entire contents of vaccine container within one hour after mixing the vaccine with the diluent.

WITHHOLDING PERIODS: NIL.

USER SAFETY INFORMATION:

Liquid nitrogen precautions:

Only properly trained personnel should handle the liquid nitrogen containers and vaccines. These persons should be familiar with AS 1894 - Code of Practice for the Safe Handling of Cryogenic Fluids and the Dangerous Goods (Storage and Handling) Regulations 1989 (S.R. No. 323/1989). Liquid nitrogen is extremely cold. Accidental contact with the skin or eyes can cause severe frostbite. Protect eyes with goggles or face shield. Wear leather gloves and long sleeves when removing and handling frozen ampoules or when adding liquid nitrogen to the container. Storage and handling of liquid nitrogen containers must be in a well-ventilated area. Excessive amounts of gaseous nitrogen reduces the concentration of oxygen in the air of an unventilated space and can cause asphyxiation.

Additional information on this product is available on the Material Safety Data Sheet.

FIRST AID:

Liquid Nitrogen

- If drowsiness occurs, get to fresh air quickly and ventilate the entire area.
- If a person becomes groggy or loses consciousness while working with liquid nitrogen, get the person to a well-ventilated area immediately.
- If breathing has stopped, begin artificial respiration. Call a physician immediately.

If poisoning occurs contact a Doctor, or Poisons Information Centre on 13 11 26

STORAGE INSTRUCTIONS:

Ampoules: Store immersed in liquid nitrogen.

Diluent: Store at room temperature.

Liquid nitrogen container: Carefully observe all liquid nitrogen precautions including wearing eye protection and leather gloves. Store in a cool, well-ventilated area. Check liquid nitrogen level daily. Keep container away from incubator intakes and chicken holding boxes.

DISPOSAL:

Discarded unused vaccine and empty vaccine bottles into a disinfectant solution (e.g. chlorine-based bleach). Dispose of any such inactivated, unused vaccine and empty containers by wrapping in paper and putting in garbage.

In cases of spillage, soak up the liquid with an absorbent sponge or cloth and incinerate. Treat the surface with a disinfectant solution (e.g. chlorine-based bleach).

CAUTION:

The capability of this vaccine to produce satisfactory results 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 individual chickens and timing/degree of field exposure. Therefore, directions for use should be followed carefully.

CONTACT DETAILS:

BIOPROPERTIES Pty Ltd
ACN 007 303 728
36 Charter Street
Ringwood
Victoria 3134, Australia
PH: 03 9876 0567 FAX: 03 9876 0556



WARRANTY AND DISCLAIMER

Vaxsafe® RIS has been tested and meets safety and potency standards according to the Standards required by the APVMA. BIOPROPERTIES Pty Ltd accepts no responsibility for events arising from the misuse or mishandling of the product. BIOPROPERTIES Pty Ltd gives no warranty (express or implied) with respect to the product, including without limitation any warranty as to completeness, merchantability or fitness for a particular purpose. Under no circumstances shall BIOPROPERTIES Pty Ltd be liable for indirect, special, consequential or punitive damages.

APVMA No: 50485/1207

Code/Version No: LFT-RIS V12