

FOR ANIMAL USE ONLY

NOBILIS® RISMAVAC

Reg. No. G2444 (Act 36/1947)

Namibia Reg. No. V98/24.3/674 NS0

Only for use by persons authorised thereto in terms of the Veterinary and Para-veterinary Professions Act, Act 19 of 1982.

INDICATIONS

Nobilis® Rismavac is a live vaccine recommended for the immunisation of healthy day-old chicks against Marek's Disease and is also indicated where virulent strains of Marek's Disease are prevalent.

COMPOSITION

Nobilis® Rismavac is a live vaccine containing Marek Disease virus serotype 1, strain CVI-988.

CONTENTS

Each dose of **Nobilis® Rismavac** contains at least 3,0 log₁₀ TCID₅₀ serotype 1, strain CVI-988, in the cell associated form, as a suspension of virus containing SPF chicken embryo fibroblasts. The vaccine contains stabilisers and antibiotics.

STORAGE

- The Vaccine containing ampoules (which are inserted in metal canes) are stored in liquid nitrogen (-100 °C or below).

Only 1 ampoule should be removed at any one time.

The cane holding the remaining ampoules should be replaced immediately in the canister of the liquid nitrogen container.

The contents of the removed ampoule should rapidly be thawed by immersing in water at room temperature (20 °C to 25 °C).

- The Liquid Nitrogen Container must be stored in an upright position in a dry, well-ventilated area away from incubator intakes and chicken boxes.
- The Diluent is stored at room temperature (20 °C to 25 °C).

WARNINGS

- Avoid intravenous injection.
- Do not mix the vaccine with other vaccines.
- Keep the frozen vaccine ampoule in liquid nitrogen until ready to vaccinate.
- Do not use vaccine that has been previously thawed other than immediately before use.
- The contents of the ampoule should be thawed by immersing in water at room temperature. Do not thaw in hot or ice-cold water. Ampoules have been known to explode on sudden temperature changes.
- Diluent: The temperature of the diluent must be at room temperature (20 °C to 25 °C) at the time of mixing.
- Liquid nitrogen containers and the vaccine should be handled by properly trained personnel only, taking into consideration the safety precautions for handling liquid nitrogen and materials at very low temperatures.
- When removing an ampoule from the cane, hold the palm of the gloved hand away from the body and face.
- Good management practice is important to reduce the exposure to Marek's Disease during the first weeks following vaccination.
- The entire contents of the bottle must be used within 2 hours of mixing.
- Do not store partially used containers for future use.
- Dispose of empty vaccine containers, all unused product and disposable vaccine equipment according to local waste disposal regulations.
- **KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.**

- Although this vaccine has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Vaccinate healthy day-old chicks only.
- Observe aseptic precautions. Ensure that vaccination equipment (needles, syringes, etc.) is clean and sterile prior to use.
- Ensure that all equipment is kept clean and sterile during vaccination.
- Sterilise vaccinating equipment by boiling in water for 20 minutes or by autoclaving (15 minutes at 121 °C).
- Do not use chemical disinfectants.
- The operator should protect the hands with gloves, wear long sleeves and use a face mask or goggles.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.
- Accidental self-injection may lead to severe local allergic reactions. Consult a physician informing him/her that the vaccine is a live vaccine and that it contains a small amount of dimethyl sulphoxide (DMSO).

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

The bottle of mixed vaccine should be kept in an ice bath and swirled frequently.

Preparation of the vaccine

- Sterilise vaccinating equipment by boiling in water for 20 minutes or by autoclaving (15 minutes at 121 °C). Do not use chemical disinfectants.
- Use contents of 1 ampoule per bottle of sterile diluent for 1 000 chicks.
- Before withdrawing the vaccine from the liquid nitrogen container, protect the hands with gloves, wear long sleeves and use a face mask or goggles. An accident might occur with either the liquid nitrogen or the vaccine ampoules. When removing an ampoule from the cane, hold palm of the gloved hand away from the body and face.
- When withdrawing a cane of ampoules from the canister in the liquid nitrogen container, expose only the ampoule to be used immediately. It is recommended only to handle 1 ampoule at a time. After removing the ampoule, the cane holding the remaining ampoules should be replaced immediately in the canister of the liquid nitrogen container.
- The content of the ampoule is rapidly thawed by immersing in water at room temperature (20 °C to 25 °C). Do not thaw in hot or ice-cold water. Dry the ampoule and gently rotate it to disperse the contents. Then break the ampoule at its neck and immediately proceed as below.
(**Caution:** Ampoules have been known to explode on sudden temperature changes).
- Draw the contents of the ampoule into a sterile 5 ml or 10 ml syringe fitted with a 1 mm (18 gauge) needle.
- Insert the needle through the stopper of the diluent bottle and dilute immediately by filling syringe slowly with a portion of the diluent.
(**Note:** The diluent should be at room temperature (20 °C to 25°C) at the time of mixing).
- The content of the filled syringe is then added to the remaining diluent. It is important that this be done slowly allowing the vaccine to run down the side of the bottle. Gently shake the bottle as the vaccine is being mixed. Withdraw a portion of the diluent with the syringe to flush the ampoule. Inject the washings back into the diluent bottle. Remove the syringe.
- Fill the previously sterilised automatic syringe according to the manufacturer's recommendations and set the dose for 0,2 ml.
- The vaccine is now ready for use.

Method of vaccination

- The vaccine is injected subcutaneously in the neck or intramuscularly in the leg.
- Inject 0,2 ml per chick.
- The bottle of vaccine should be kept in an ice bath and swirled frequently.
- The entire contents of the bottle must be used within 2 hours of mixing and any remaining vaccine should be discarded according to local waste disposal regulations.

PRESENTATION

Glass ampoules containing 1 000 doses or 2 000 doses of vaccine, and 200 ml or 400 ml of sterile diluent.

REGISTRATION HOLDER

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