

FOR ANIMAL USE ONLY

NOBILIS® RISMAVAC + CA126

Reg. No. G2632 (Act 36/1947)

Namibia Reg. No. V05/24.3/659 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 + CA126 is a combined live, cell-associated Marek's Disease vaccine recommended for the immunisation of healthy chicks against Marek's Disease.

COMPOSITION

Nobilis® Rismavac + CA126 is a combined live vaccine containing FC-126 (serotype 3) strain of Turkey Herpes Virus and CVI-988 (serotype 1) strain of Fowl Herpes Virus.

CONTENTS

Each dose of **Nobilis® Rismavac + CA126** contains at least 3,0 log₁₀ PFU of live Turkey Herpes Virus strain FC-126 (serotype 3) and at least 3,0 log₁₀ PFU of live Fowl Herpes Virus strain CVI-988 (serotype 1) in the cell-associated form, as a suspension of virus containing SPF chicken embryo fibroblasts.

STORAGE

- The vaccine containing ampoules (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 between 20 °C and 25 °C.

WARNINGS

- Keep the frozen vaccine ampoule in liquid nitrogen until ready to vaccinate.
- When removing an ampoule from the cane, hold the palm of the gloved hand away from the body and face.
- 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.
- Do not use vaccine that has been thawed other than immediately before use.
- 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.
- It is good vaccination practice when handling vaccines to avoid contact with the eyes, hands and clothing.
- The bottle of mixed vaccine should be kept in an ice bath and swirled frequently.
- Diluent: The diluent must be at room temperature between 20 °C and 25 °C at the time of mixing.
- Good management practice is important to reduce the exposure to Marek's Disease during the first weeks following vaccination.
- The operator should protect the hands with gloves, wear long sleeves and use a face mask or goggles.

- Accidental self-injection may lead to severe local allergic reactions. Consult a physician informing him/her that the **Nobilis® Rismavac + CA126** is a live vaccine and that it contains a small amount of dimethyl sulphoxide (DMSO).
- Do not mix **Nobilis® Rismavac + CA126** with other vaccines.
- The entire contents of the bottle must be used within 2 hours of mixing.
- Do not store partially used containers for future use.
- Destroy any unused, mixed vaccine, empty vaccine containers, needles, etc. as per local waste disposal regulations after completion of the vaccination.
- **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.) are clean and sterile prior to and during use.
- Sterilise vaccination equipment by boiling in water for 20 minutes or by autoclaving for 15 minutes at 121 °C.
- Do not use chemical disinfectants.
- Avoid intravenous injection.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

Preparation of the Vaccine

- Sterilise vaccination equipment by boiling in water for 20 minutes or by autoclaving for 15 minutes at 121 °C. Do not use chemical disinfectants.
- Use contents of 1 ampoule of the vaccine 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 contents of the ampoule is rapidly thawed by immersing the water at room temperature between 20 °C and 25 °C. Do not thaw in hot or ice-cold water. Dry the ampoule and shake 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 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 between 20 °C to 25 °C at the time of mixing).
- The contents of the filled syringe are 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.

Dosage and administration

- The vaccine is injected subcutaneously in the neck.
- 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.
- Any remaining vaccine should be discarded according to local waste disposal regulations.

PRESENTATION

Glass ampoules containing 1 000 doses of vaccine and 200 ml of sterile diluent.

REGISTRATION HOLDER

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