FOR ANIMAL TREATMENT ONLY

Vaxsafe[®] ND Vaccine (living)

ACTIVE CONSTITUENT: Each dose contains $\geq 10^{5.7}$ EID₅₀ avirulent Newcastle Disease Virus (NDV) StrainV4, living. *EID = Egg Infectious Dose

STATEMENT OF CLAIMS: A freeze-dried vaccine for the prevention of Newcastle disease in broiler chickens.

The vaccine may be given to chickens from seven (7) days of age orally through the drinking water. Chicks should have maternal haemagglutination inhibition (HI) antibody titre to NDV of $\leq 2^{3.0}$ at the time of vaccination for an optimal response.

1000 / 2000 / 3000 / 4000 / 5000 / 10,000 / 20,000 Doses

CONTENTS: The product consists of a freeze dried pellet in a 3 mL glass vial containing 1000, 2000, 3000, 4000 or 5000 doses per vial OR a freeze dried pellet in a 10 mL glass vial containing 5000, 10,000 or 20,000 doses per vial.

READ DIRECTIONS CAREFULLY

DIRECTIONS FOR USE:

Use of this vaccine may be restricted in your state or territory. It may only be supplied to those persons or their nominated veterinarian who have been authorised to use it by their State Chief Veterinary Officer or Chief Inspector of Stock (or their nominated delegate). Contact your local Department of Agriculture (or similar) for details.

Contraindications:

 This product is contraindicated for vaccinating unhealthy birds.

Precautions:

- Administer only as directed and use entire contents when first opened.
- · Always keep the vaccine cool and away from sunlight.
- Vaccinate all chickens at the one time and administer a full dose to each chicken.
- Early morning vaccination is recommended to ensure rapid consumption of water by the birds in conditions of temperature and light most favourable for effective vaccination and minimum stress to the flock.
- Vaccine must be consumed within two hours of preparation.
- Maintain chickens under good husbandry and environmental conditions and minimise exposure to stressful conditions and disease causing viruses especially during the first two weeks after vaccination.
- Wash and disinfect hands after use.

Indications:

Vaccination in the presence of maternal antibodies may delay the onset, and reduce the magnitude, of active immunity development. Monitoring of HI antibody levels in the serum of chickens is recommended. Antibody levels should be $\geq 2^{3.0}$ to protect against mortality.

Dosage and Administration:

Broiler Chickens

Vaxsafe ND can be administered to broiler chickens from 7 days of age. The preferred program is to administer the vaccine once between 7 and 14 days of age.

Method of Vaccination:

Preparation of Vaccine for Drinking Water Administration

- Rainwater or clean bore/dam water should be used, if available, to prepare vaccine. Avoid heavily chlorinated water if possible. If chlorinated water is used, it should be left to stand overnight to permit the chlorine to dissipate.
- No medication, disinfectants or detergents should have been used in the containers for mixing the vaccine or in the drinking system for 48 hours before vaccination.
- Skim milk powder, when used as recommended, acts as a stabiliser and protects the live virus in the vaccine.
- Calculate the total number of doses of vaccine required, based on the total bird number of chickens in the shed rounded up to the nearest whole vial.
- Remove the number of vials required from the deep freeze to a dust-free area out of direct sunlight.
- Prepare a small volume (1 litre) of tap water containing 2.5 g/L of skim milk powder in a screw capped container to act as the diluent for the vaccine.
- Remove the caps and stoppers from the vials.
- Using a 5 or 10 mL syringe, dissolve each plug of freezedried vaccine with about 2-3 mL of the prepared diluent.
- Withdraw the dissolved contents from all of the vials back into the diluent container.
- Shake the container well and hold in the refrigerator until ready for use.
- Vaccine should be administered as soon as possible after preparation.
- Only use a plastic bucket and utensils to prepare vaccine.

Preparation of Diluent

• Select a suitable container depending upon the chosen method of drinking water vaccination (medication tank or directly into drinkers) and mix skim milk powder with clean water at the rate of 2.5 g of powder to 1 litre of water.

Vaccination Procedure

 Vaccine may be administered to chickens through the drinking water using a medication tank method or by directly dispensing into the drinking fonts.

Medication Tank Method

- Do not administer any medication or disinfectants in the drinking water within 48 hours prior to or following vaccination.
- Determine the drinking water consumption of the chickens over a two-hour period on the day before vaccination.
- On the morning of the day of vaccination, turn off the main water supply and thoroughly clean all drinking fonts. Do not use disinfectants during cleaning.
- The medication tank should be emptied and cleaned. Do not use disinfectants during cleaning.
- Fill the medication tank with the amount of water that you calculated would last the chickens two hours of water consumption. Add skim milk powder at the rate of 2.5 g/L and mix this thoroughly with the fresh water in the tank.
- Tip the previously prepared vaccine into the tank and again mix thoroughly.
- Turn on the medication tank and drain off any clear water until the water containing the skim milk powder and vaccine appears as a cloudy white colour. Allow the drinkers to fill and then encourage all the chickens to consume the vaccine/water.
- Continue to encourage consumption of all of the vaccine/ water over the next two hours.
- Turn on the main water supply only after all of the vaccine mixture has been consumed.

Directly into Drinking Fonts

- As described above, determine the water consumption of the chickens over two hours.
- Turn off the main water supply and then clean, rinse and empty the water troughs.
- Avoid the use of disinfectants or detergents during cleaning.
- Prepare the vaccine initially in a one-litre volume as described above.

- Prepare a larger volume of water (eg in a clean plastic garbage bin) equivalent to the volume of water that the birds will consume over a two-hour period. Add skim milk powder at the rate of 2.5 g/L and mix thoroughly.
- Mix in the previously prepared vaccine and thoroughly stir the mixture.
- Distribute the vaccine mixture with a clean container to all the drinking fonts in the shed.
- Encourage the birds to drink and ensure that the fonts continue to be topped-up until all the vaccine/water is consumed.
- The vaccine/water should be consumed within two hours.
- Ensure that the chickens only have access to the vaccine/water and not to any other water supplied during this two-hour period.

WITHHOLDING PERIOD: NIL.

USER SAFETY INFORMATION:

Newcastle disease vaccines can cause conjunctivitis if accidentally splashed or sprayed into the eyes of an operator. Eye protection should, therefore, be worn when handling vaccine, and medical advice sought if accidental contact with the eyes occurs.

Additional information is available in the product specific Material Safety Data Sheet.

FIRST AID:

- If swallowed, rinse mouth with clean, fresh water and swallow some clean water.
- If splashed into the eye, hold eyes open and gently wash material from them with clean running water. Ensure irrigation under eyelids by lifting them. Do not attempt to remove contact lenses unless trained to do so.
- If skin becomes contaminated, wash affected area with soap and water. If irritation occurs, seek medical advice
- If inhaled, remove person to fresh air and observe until recovered. If irritation or other symptoms persist, seek medical advice.

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

STORAGE INSTRUCTIONS:

Store below -18°C (deep freeze).

DISPOSAL:

Dispose of vials/containers should immediately a designated and appropriately labelled 'biologicals' container. If this option is not available, discard unused vaccine and empty vaccine vials 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 degree of field exposure. Therefore, directions for use should be followed carefully.

CONTACT DETAILS:

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WARRANTY AND DISCLAIMER

Vaxsafe ND 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: 59142/136578 Code/Version No: LFT-ND V5