RLP
APPROVED

Product Name: NOBILIS GUMBORO + ND COMBINED INACTIVATED VACCINE AGAINST GUMBORO AND NEWCASTLE DISEASE

APVMA Approval No: 58353/132518

Label Name:	NOBILIS GUMBORO + ND COMBINED INACTIVATED VACCINE AGAINST GUMBORO AND NEWCASTLE DISEASE

Signal Headings:	FOR ANIMAL TREATMENT ONLY

Constituent Statements:	ACTIVE CONSTITUENTS: NDV Clone 30 inducing ≥ 4 log2 HI units per 1/50th of a dose or containing ≥ 50 PD50 units/dose; IBDV D78: inducing ≥ 14.5 log2 VN units/dose in an oil adjuvanted emulsion. Nobilis® GUMBORO + ND contains one immunogenic strain of Newcastle Disease virus and one immunogenic strain of Infectious Bursal Disease virus. The viruses have been grown on embryonated eggs or Vero Cell cultures and are inactivated with formalin. Subsequently they have been suspended in the aqueous phase of an oil adjuvant emulsion.

Claims:	Inactivated vaccine for the protection of chickens against Infectious Bursal Disease and poultry against Newcastle Disease.

Net Contents:	500 mL (1000 doses)

Directions for Use:	

Restraints:	Do not mix with other vaccines.

Contraindications:	

Precautions:	Vaccinate healthy birds only.

Side Effects:	Vaccination reactions:

	In healthy birds no clinical reaction to vaccination will be observed. For some weeks after vaccination a slight swelling may be felt at the site of vaccination. Local tissue reactions may occur.

Dosage and Administration:	Shake the bottle well before and during use. Broached vials should be used within 3 hours. Before using vaccine allow it to reach an ambient temperature (15°C to 25°C). Use sterile injection equipment. Each bird should be given 0.5 mL of vaccine intramuscularly (IM) in the thigh or chest muscle or subcutaneously (SC) into the lower part of the neck. Recommended vaccination program: Nobilis GUMBORO + ND should be given to birds around 14-18 weeks of age but not less than 4 weeks before the expected onset of lay. For an optimal booster effect, the birds must be previously primed with live vaccines against Newcastle Disease and Infectious Bursal Disease. The best results will be obtained if vaccination with Nobilis GUMBORO + ND vaccine takes places 6 or more weeks after administration of the live vaccine but in no circumstances should it be done earlier than 4 weeks after priming.

General Directions:	Immunity: If priming and subsequent vaccination have been carried out correctly the birds will develop antibodies at a level which provides protection against Newcastle Disease. Under normal field situations, the offspring born at any stage of the laying period will have sufficient maternal antibodies to protect them against disease caused by Gumboro infections during the first weeks of life.

Withholding Periods:	Zero (0) days.

Trade Advice:	

Safety Directions:	

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

First Aid Warnings:	

Additional User Safety:	Take care to avoid accidental self-injection. This product contains a mineral oil and is an irritant. In the event of accidental self-administration, it can cause significant pain and swelling at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required, especially if the site of injection involves a finger joint or tendon sheath. Contact a doctor as soon as possible, even if only a very small amount is injected, and take this package leaflet/ carton with you. Allow the wound to bleed freely and do not squeeze or interfere with the injection site to avoid spread of the vaccine. Advice to the medical practitioner

	This product contains mineral oil. Even if small amounts of this product have been accidentally self-administered, it can cause intense swelling and a persistent granulomatous inflammatory reaction. If injected into a finger joint or tendon sheath, the product may track along the tendon. The swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit. Following appropriate immediate local cleansing, corticosteroids may be considered to decrease the severity of any local reaction. Ascertain the patient's tetanus immunisation status, and provide booster or primary series, as appropriate. In some cases of accidental self-injection, PROMPT surgical attention may be required. The wound should be incised and irrigated to remove the vaccine, especially where there is involvement of finger pulp or tendon. Complete curettage or total excision of the lesion may be required for chronic granulomatous reactions. Meticulous technique is required to stop inadvertent spread of the product. Additional information is listed in the safety data sheet.

Environmental Statements:	

Disposal:	Dispose of empty container by wrapping with paper and putting in garbage. Discarded needle/sharps should be placed in a designated and appropriately labelled 'sharps' container.

Storage:	KEEP OUT OF REACH OF CHILDREN Store between 2°C and 8°C (refrigerate, do not freeze).