

Product Name: NOBILIS GUMBORO INACTIVATED VACCINE
APVMA Approval No: 49421/132512



Label Name:	NOBILIS GUMBORO INACTIVATED VACCINE
Signal Headings:	FOR ANIMAL TREATMENT ONLY
Constituent Statements:	<p>Inactivated Infectious Bursal Disease Virus (Strain IBDV D78): inducing $\geq 14.5 \log_2$ VN units, in oil emulsion adjuvant.</p> <p>Contains virus grown on Vero Cell cultures, inactivated with formalin and subsequently suspended in the aqueous phase of an oil adjuvant emulsion.</p> <p>Contains one immunogenic strain of Infectious Bursal Disease Virus.</p>
Claims:	<p>Inactivated vaccine for the protection of chickens against Infectious Bursal Disease.</p> <p>The vaccine is recommended for the booster vaccination of breeding stock against Infectious Bursal Disease virus in order to protect the offspring of the vaccinated birds against Infectious Bursal Disease (also known as Gumboro Disease).</p>
Net Contents:	500 mL
Directions for Use:	
Restrains:	Do not mix with other vaccines.
Contraindications:	
Precautions:	<ul style="list-style-type: none">• Caution: Avoid carcass damage• Vaccinate healthy birds only.
Side Effects:	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:	<p>Shake the bottle well before use. Broached vials should be used within 3 hours.</p> <ul style="list-style-type: none"> • Before using vaccine allow it to reach ambient temperature (15 °C-25 °C). • Sterilise all injection apparatus by boiling before use. Avoid use of strong disinfectants on apparatus. Do not use equipment that has not had sufficient time to cool to room temperature. Allow a minimum of 30 minutes to cool after boiling. • Maintain cleanliness at all times. • Use needles of appropriate gauge and length. Keep needles sharp and clean; replace frequently. • Each bird should be given 0.5 mL of vaccine intramuscularly in the thigh or breast muscle or subcutaneously into the lower part of the neck. <ul style="list-style-type: none"> • Nobilis GUMBORO should be given to birds approximately 16-20 weeks of age but not less than 4 weeks before the expected onset of lay. • For an optimal booster effect, the birds must be primed with live vaccines against Infectious Bursal Disease. • The best results will be obtained if vaccination with inactivated vaccine takes place six or more weeks after administration of the live primer but in no circumstances should it be done earlier than four weeks after priming.
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General Directions:	<p>Immunity: When priming and subsequent vaccination have been carried out correctly, the offspring born at any stage of the laying period will, under normal field situations, have sufficient maternal antibodies to protect them against disease caused by Gumboro infections during the first weeks of life.</p>
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Withholding Periods:	Zero (0) days.
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Trade Advice:	
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Safety Directions:	
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
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First Aid Warnings:	
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Additional User Safety:	<p>Take care to avoid self-injection</p> <p>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.</p> <p>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</p>
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	<p>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.</p> <p>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.</p> <p>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.</p> <p>Additional information is listed in the safety data sheet.</p>
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Environmental Statements:	
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Disposal:	Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.
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Storage:	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>Store between 2°C and 8°C (refrigerate, do not freeze).</p>
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