

TEMPLATE FOR RELEVANT LABEL PARTICULARS (RLPs) (Veterinary Products)

APVMA No: 35759
Product Name: Nobilis® IB Vaccine

Date: 1st November 2012

Select appropriate:

☐ New Product (include all applicable RLPs) OR

☒ Variation (highlight instructions that are being varied). Approval no. of label being varied: 35759/52971



Label Components include in product label: Vial and Carton

Label Particular	Text	Label components
Signal heading:	FOR ANIMAL TREATMENT ONLY	Vial, Carton front and inner lid panel
Product name:	Nobilis® IB Vaccine	Vial, Carton front and inner lid panel
Active constituent/s:	Vial: Infectious Bronchitis virus living, attenuated Carton front and inner lid panel: Active Constituent: Infectious Bronchitis Virus, living, attenuated (Ref. 1/197/A). Minimum titre at end of shelf life 10 ^{3.0} EID ₅₀ / per dose. Preservatives: Nil	As specified.
Statement of claims:	For the prevention of Infectious Bronchitis disease in chickens, by administration at day-old to chickens hatched from parent stock which have been vaccinated against Infectious Bronchitis.	Carton front and inner lid panel
Net contents:	Vial: Doses per 4.5mL vial – Refer to pack Carton: Contents: 1 to 25, 50 vials x 5000 or 10000 dose vials <input type="checkbox"/> No. of vials	As specified.
Directions for Use Heading:	Vial: READ INFORMATION INSIDE PACK BEFORE USE.	As specified.

Label Particular	Text	Label components
	<p>Carton Front Panel: READ THE INFORMATION PRINTED ON THE INSIDE OF THE PACK BEFORE USING THIS PRODUCT.</p> <p>Carton Inner Lid Panel: DIRECTIONS FOR USE:</p>	
Restrains:	Not required.	
Contraindications:	Not required.	
Precautions:	<p>Precautions:</p> <p><i>* It is recommended that the vaccine be diluted in 1.5-2.5% w/v non-fat skim milk powder in water, in order to neutralise any residual chlorine in the tap water. Any chlorine present could be harmful to the vaccine virus. Higher concentrations of powder will not affect the vaccine but could cause difficulties with administration.</i></p>	Carton Inner Lid Panel
Side effects:	Not required.	
Dosage & administration:	<p>Reconstitution of Vaccine:</p> <ol style="list-style-type: none"> 1) Contains 4.5 mL of lyophilised vaccine per vial – equivalent to doses indicated on the front of this pack. 2) For each vial of vaccine, prepare a sterile 5 mL syringe with one 18G x 35 mm needle attached. 3) The vaccine is rehydrated and diluted with a 1.5-2.5% w/v solution of non-fat skim milk powder in water. 4) Wipe vial dry and remove cap and plug. 5) Using the syringe, draw up 4.5 mL of the skim milk solution and transfer it immediately into the vaccine vial. Gently agitate the fluid in the vial until the entire pellet is fully dissolved and the vaccine is a uniform suspension. 6) The vaccine may now be administered in either of two ways (Spray or Drinking Water). <p>Dosage and Administration:</p> <p>USE ALL PRODUCT WITHIN 30 MINUTES OF RECONSTITUTION.</p> <p>Do not attempt to refreeze or reuse unused vaccine at a later time. Keep</p>	Carton Inner Lid Panel

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	<p>reconstituted product out of direct sunlight. Do not heat in any way.</p> <p>A) Spray Vaccination (Recommended): NB: All utensils should be clean and free of toxic agents such as petroleum products etc. 1) Transfer all the reconstituted vaccine to the spray bottle cabinet. For each 5000 doses of vaccine, dilute to 250 mL with the skim milk solution and gently mix. 2) Spray the vaccine onto day-old chickens in chick boxes. 3) Continue to spray until all the vaccine is used.</p> <p>B) Drinking Water Vaccination 1) Remove the birds' drinking water about 30 minutes prior to vaccination. 2) Then pour the reconstituted vaccine (5, above) into the birds' drinking water.</p> <p><i>The aim is to supply at least thirty minutes drinking (but no more than two hours) to all birds. This is dependent upon climate but, as a guide, 5 litres of prepared vaccine per 5000 day-old chickens per hour at 36°C.</i></p>	
General directions:	Not required.	
Withholding Period/s:	WITHHOLDING PERIOD: Zero (0) days	Vial, Carton front and Inner Lid Panel
Trade Advice:	TRADE ADVICE: EXPORT SLAUGHTER INTERVAL(ESI): ESI not required	Carton Inner Lid Panel
Safety Directions:	SAFETY DIRECTIONS: Wear chemical goggles, plastic gloves and a mist spray filter if administering by spray vaccination if an enclosed spray cabinet is not used. Additional information is contained in the Material Safety Data Sheet.	Carton Inner Lid Panel
First Aid:	FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. <i>Phone Australia 131126.</i>	Carton Inner Lid Panel

Label Particular	Text	Label components
Additional user safety:	Not required.	
Environmental statements:	Not required.	
Disposal:	DISPOSAL: Dispose of empty containers by wrapping in paper and putting in garbage. Unused product should be disposed of into an effluent handling system (e.g. septic tank). Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.	Carton Inner Lid Panel
Storage:	Vial and Carton Front Panel: Store below -18°C (deep freeze). Carton Inner Lid Panel: STORAGE: Protect from light. Store below -18°C (deep freeze). Correct storage of this vaccine is essential to ensure it is potent at the time of use. Store the vaccine vials in a deep freeze or the freezing compartment of the refrigerator. Place the vaccine in a cool box with ice on removal from the deep freeze until ready to reconstitute for use.	As specified.
APVMA Approval No.:	APVMA Approval No.: 35759/56482	Vial and Carton front panel
Batch and Expiry	B Exp.	Vial and Carton side Panel 1
Name & address:	MSD Animal Health Intervet Australia Pty Limited 91 – 105 Harpin Street Bendigo East VIC 3550 Customer Service: Ph: 1800 033 461 Fax: 1800 817 414	Carton Front and Inner Lid Panel

The following is for APVMA use only:

APVMA approval no.

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