

## FOR ANIMAL USE ONLY

### NOBILIS® IB 4-91

Reg. No. G4031 (Act 36/1947)

Namibia Reg. No. V13/24.3/1200 NS0

**This vaccine may only be used by persons registered in terms of or authorised in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).**

### INDICATIONS

**Nobilis® IB 4-91** is a live attenuated, freeze-dried vaccine against Infectious Bronchitis virus serotype 4-91 or serologically related types for administration to 1-day-old chicks and older chickens (broilers, breeders, layers).

### COMPOSITION

Each dose contains at least  $\log_{10}$  3,6 EID<sub>50</sub> of live attenuated avian Infectious Bronchitis Virus (IBV) strain 4-91 in stabiliser.

### STORAGE

- Store in the dark between 2 °C and 8 °C.
- Do not freeze.
- Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.
- The vaccine should be used within 2 hours after reconstitution and should not be stored.
- Protect from exposure to direct sunlight.

### WARNINGS

- **Withdrawal period** Meat - 21 days.
- Vaccinate healthy chickens only.
- In case of accidental ingestion, especially in the case of children, seek medical advice and show the package insert or the label to the physician.
- In case of accidental spillage onto skin, immediately wash with soap and water.
- If the product gets into the eyes accidentally, flush thoroughly with plenty of water.
- Wash and disinfect hands and equipment after vaccinating.
- Do not eat, drink or smoke while handling the product.
- Protect the reconstituted vaccine from direct sunlight.
- The vaccine virus can spread to non-vaccinated birds. Infection of non-vaccinated chickens with vaccine virus released from vaccinated birds does not induce disease in the contact animals. Thus, virus spread to non-vaccinated chickens can be considered safe.
- Dispose of unused vaccine, empty vaccine containers and vaccination equipment according to local waste disposal regulations.
- **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

- Since the stability of IBV in suspension may be low, water used for dissolving the freeze-dried vaccine should be cool and of good quality.
- The vaccine should be used within 2 hours after reconstitution and should not be stored.
- Do not mix **Nobilis® IB 4-91** with other products.
- **Nobilis® IB 4-91** is intended to protect chickens against IBV serotype 4-91 and related types only. Chickens should be vaccinated against other prevalent IBV serotypes (e.g. Massachusetts) according to the local IB vaccination program.

**Nobilis® IB 4-91** given to day-old chickens may adversely affect the efficacy of Turkey Rhinotracheitis (TRT) vaccine when given within 7 days; thus, TRT should not be used within 14 days of **Nobilis® IB 4-91**.

#### **DIRECTIONS FOR USE - USE ONLY AS DIRECTED**

Do not open and reconstitute the vaccine until ready to start vaccination.  
Reconstituted vaccine should be used within 2 hours after reconstitution.

#### **Recommended Vaccination Programme**

The vaccine can be administered to day-old chicks and older chickens by coarse spray or by administration via the intranasal/ocular route.

The vaccine can be administered to chickens of 7 days and older, via drinking water.  
For prolonged immunity, chickens should be revaccinated 6 weeks after the initial administration.

#### **Dosage and Administration**

The optimum time and method of administration depend largely upon the local situation and veterinary advice should be sought on a site basis.

The vaccine may be administered by coarse spray, drinking water or via the intranasal/ocular route.

#### **A. Spray Method**

The vaccine should be dissolved in distilled water. Where the number of birds is between the standard dosages, the next higher dosage should be used. The appropriate number of vials should be opened under the surface of the water. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds.

This will vary according to the age of the birds being vaccinated and the management system, but 250 to 400 ml of water/1 000 doses is suggested.

The vaccine suspension should be spread evenly over the correct number of birds, at a distance of 30 to 40 cm using a coarse spray (like falling rain), preferably when the birds are sitting together in dim light.

The spray apparatus should be free from sediments, corrosion and traces of disinfectants (dedicated for use for vaccination purposes only).

#### **B. Drinking Water**

##### **Reconstitution of vaccine**

The vaccine is presented in vials under vacuum.

Measure the correct volume of water for the number of birds to be vaccinated (see below) and open the adequate number of containers of vaccine (vials under the surface of the water).

Where the number of birds is between the standard dosages, the next higher dosage should be used. All containers used, should be clean and free from any traces of detergent or disinfectant.

Use distilled water.

Mix thoroughly with a clean stirrer, ensuring that all containers used are emptied.

Offer to birds immediately.

Where water sanitisers are used, the registration holder, Intervet South Africa (Pty) Ltd. technical staff should be contacted.

Vac-Safe® is an effervescent tablet that contains a blue colourant and a chlorine neutralising agent. Added to poultry drinking water while vaccinating with live vaccines, Vac-Safe® allows the user to protect the vaccine against chlorine in drinking water, to control the delivery of the vaccine solution within the water network and to evaluate the vaccine intake directly on the birds. There should be a 10 minute waiting period after adding Vac-Safe® to the water, before adding the contents of the **Nobilis® IB 4-91** vials.

##### **Volumes of water for reconstitution of vaccine**

The volume of water for reconstitution depends on the age of the birds and the management practice.

### **Simple drinking troughs and fountains**

The following are guidelines 1 000 doses/ℓ per age in days up to a maximum volume of 20 ℓ/1 000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 ℓ/1 000 doses.

### **Nipple drinkers**

Drinker line management is known to have a significant effect on the viability of live vaccine virus.

The vaccine virus can deteriorate very rapidly, and it is essential to ensure that all birds receive the correct dose.

Special care should be taken concerning the method of administration, for example, small header tanks may require recharging with medicated water several times during a 1 to 2 hour period.

### **Administration**

Water should be withheld before vaccination.

For recommendations see *Management* below.

Ensure that all the vaccine suspension is consumed within 1 to 2 hours.

Turn on main water when all the vaccine water has been consumed.

Always ensure that there is feed available when vaccinating. Birds will not drink if they have no feed to eat. Water intake is directly correlated to feed intake.

### **Management**

Great care should be taken to ensure that all birds receive a full dose of vaccine when the product is administered.

The following points have been found to improve vaccine "take"

1. Water withholding should be kept to a minimum. Approximately 1 hour is all that is required if the following management techniques are used.
2. Try to vaccinate at a time when birds are likely to be drinking, e.g. when feed is in the feed tracks.
3. Turn the lights down low when the water is turned off. For bell drinkers, go around the house emptying and cleaning the drinkers during the 1-hour period of low lights. Mix the vaccine according to the recommendations, and towards the end of the 1-hour water withholding period, go around all the drinkers filling each with water containing vaccine. Leave the house and turn the light up. The increased light intensity will stimulate the birds to look for water and feed. Therefore, it is important that feed is available, or the birds will not be interested in drinking. In some cases, it helps to run feed tracks at the time the light intensity is increased. For nipple lines, a substantial volume of residual water may remain in the lines after the 1-hour water withholding/dark period. It is advisable to drain the lines and prime with vaccine-loaded water before allowing the birds to have access to the drinking lines. Mix up the vaccine and apply to the header tank(s). Calculate the volume of water that is left in the tank below the outlet valve and make sure you add extra vaccine to this volume of water, for example, if 10 ℓ remain below the outlet pipe and you are using 10 ℓ/1 000 birds to vaccinate, add 1 000 doses extra vaccine when mixing up vaccine for that tank. The use of this extra vaccine is important.
4. The vaccine should be dissolved in an amount of water which will be consumed by the animals within approximately 2 hours. Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination and will be less stressful to the birds.

### **C. Intranasal/Eye drop Administration**

Dissolve the vaccine in physiological saline solution or sterile distilled water (usually 30 ml/1 000 doses, 75 ml/2 500 doses) and administer by means of a standardised dropper.

One drop should be applied onto 1 nostril or 1 eye.

The handler should ensure that the nasal drop is inhaled before freeing the bird.

**Note** For intranasal/eye drop administration a special diluent, Diluent Oculo Nasal, is available. Dissolve the vaccine with either 36 ml for 1 000 doses or 90 ml for 2 500 doses.

Coarse spray or intranasal/ocular administration gives the best response.  
These should be the methods of choice, especially when vaccinating young birds.

### **IMMUNITY**

After vaccination, an adequate immunity against Infectious Bronchitis serotype 4-91 and serologically related serotypes will last for at least 6 weeks, provided that the vaccine is properly administered. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

For further information on use of a vaccine in specific circumstances or in conjunction with other Intervet South Africa vaccines, consult Intervet South Africa's technical staff.

### **VACCINATION REACTIONS**

Vaccination with **Nobilis® IB 4-91** may induce a mild respiratory reaction for a few days and is dependent on the health and condition of the birds. Good hygiene and management are also important factors in order to minimise vaccination reactions.

### **PRESENTATION**

Glass vials containing 1 000, 2 500 or 5 000 doses.

### **REGISTRATION HOLDER**

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### **MANUFACTURER**

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