

# Nobilis IB 4-91 Data Sheet

## Presentation

Live, freeze-dried virus vaccine containing Infectious Bronchitis virus strain 4-91 plus stabilisers and traces of gentamicin. Each dose contains IB virus strain 4-91\*3.6 log<sub>10</sub> EID<sub>50</sub>.\*

\*EID<sub>50</sub> = 50% Embryo Infective Dose: the titre required to infect 50% of the embryos inoculated with the virus.

## Uses

Active immunisation of chickens to reduce the respiratory signs of Infectious Bronchitis caused by the variant strain of IB 4-91.

## Dosage and administration

At least 3.6 log<sub>10</sub> EID<sub>50</sub> (1 dose) per animal by either spray vaccination, drinking water or intranasal/ocular administration. Where the number of chickens is between the standard dosages, the next higher dosage should be used.

### Spray method

The vaccine should preferably be dissolved in distilled water or alternatively in cool, clean water. The appropriate number of vials should be opened under water. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the chickens. This will vary according to the age of the chickens being vaccinated and the management system, but 250 to 400 ml of water per 1000 doses is suggested. The vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30–40 cm using a coarse spray, preferably when the chickens are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (and ideally should be used for vaccination purposes only).

### Drinking water

The vials should be opened under water. Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1000 doses in one litre per age in days up to a maximum volume of 20 litres per 1000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 40 litres per 1000 doses. By adding approximately 2 grams of skimmed milk powder or 20 ml liquid skimmed milk per litre of water the virus retains its activity longer. Ensure that all the vaccine suspension is consumed within 1-2 hours. The vaccine should be given in the early morning as this is the main period of water intake or during the cool period on a hot day. Feed should be available when vaccinating. Water should be withheld before vaccination to make the chickens thirsty. The length of time of water deprivation is strongly dependent on climatological circumstances. Water withholding should be kept as short as possible with a minimum of half an hour. A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergents and disinfectants. Turn on mains water when all the vaccine water has been consumed.

### Intranasal/ocular administration

Dissolve the vaccine in physiological saline solution or sterile distilled water (usually 30 ml per 1000 doses, 75 ml per 2500 doses) and administer by means of a standardized dropper. One drop should be applied onto one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Intranasal/ocular administration or coarse spray gives the best response and these should be the methods of choice, especially when vaccinating young chickens.

### Vaccination programme

The veterinary surgeon should determine the optimum vaccination schedule according to the local situation.

## Guidelines

### Broilers

The vaccine can be administered to 1-day-old chicks and older chickens by coarse spray or by intranasal/ocular administration. The vaccine can be administered to 7-day and older chickens by drinking water. For prolonged immunity, chickens should be re-vaccinated every 6 weeks after the initial administration.

### Future layers and breeders

The vaccine can be administered to future layers and breeders from three weeks of age onwards via intranasal/ocular route, coarse spray or drinking water.

## Other information

Since the stability of IBV in suspension may be low due to sensitivity to high temperatures and impurities, water used for the freeze-dried vaccine should be cool and of good quality. By adding skimmed milk to the drinking water the vaccine virus retains its activity longer. Only skimmed milk should be used, since fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

The vaccine should be used within 2 hours after reconstitution and should not be stored.

Do not mix or administer with other products.

Only healthy chickens should be vaccinated.

Nobilis IB 4-91 is intended to protect chickens against respiratory signs of disease caused by IBV variant strain 4-91 only and should not be used as a replacement for other IBV vaccines. Chickens should be vaccinated against other prevalent IBV serotypes (e.g. Massachusetts) according to the local IB vaccination programme.

The product should only be used after it has been established that IBV variant strain 4-91 is epidemiologically relevant in the area. Care should be taken to avoid the introduction of the variant strain into an area where it is not present.

## Contra-indications, warnings, etc

Nobilis IB 4-91 given at day-old can adversely affect the efficacy of Turkey Rhinotracheitis (TRT) vaccine given within 7 days, therefore this vaccination scheme is contra-indicated.

Future layers and breeders should not be vaccinated before 3 weeks of age.

The vaccine virus may spread from vaccinates to non-vaccinated chickens and appropriate care should be taken to separate vaccinates from non-vaccinates. Care should be taken to avoid spread of a vaccine virus from vaccinates to pheasants.

Vaccination with Nobilis IB 4-91 may induce mild respiratory signs, which may persist for a few days, depending on the health and condition of the chickens.

### Operator warnings

1. Wash and disinfect hands after use.
2. When spraying the vaccine, to avoid hay-fever like reaction in some individuals, well fitting respirator masks, and eye protection, to the appropriate current British/European standard, must be worn by the operator and staff.

### Withdrawal period

Zero days.

For animal treatment only. Keep out of the reach of children.

## Pharmaceutical precautions

Store between +2° and +8°C. Do not freeze. Protect from light.

Vaccine medicated water should be used immediately and not be stored.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

## Legal category

POM.

#### Further information

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure and variant challenge, fully immune chickens may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

#### Marketing authorisation numbers

EU2/98/006/001	10 ml bottle containing 1000 doses
EU2/98/006/002	10 ml bottle containing 2500 doses
EU2/98/006/003	10 ml bottle containing 5000 doses
EU2/98/006/005	10 bottles of 10 ml containing 1000 doses
EU2/98/006/006	10 bottles of 10 ml containing 2500 doses
EU2/98/006/007	10 bottles of 10 ml containing 5000 doses