



Avian Infectious Bronchitis Vaccine, Live, I.P.

Nobilis® IB 4-91

1 000

1 000 doses



sphereon®

NOT FOR HUMAN USE; FOR ANIMAL TREATMENT ONLY

WARNING: To be sold by retail on the prescription of a "Veterinary Doctor" only



MSD

Animal Health

Manufactured by

Intervet International B.V.
Boxmeer, The Netherlands.

Imported and Marketed by

Intervet India Pvt. Ltd., Bldg. No. B-1, Godown No.12 To 16, Ground Floor &
Godown No. 12-A to 17-A First Floor, House No. 233, Sagar Complex, Owali, Bhiwandi-14,
Thane-421302, Maharashtra, India.

797408 R4

Avian Infectious Bronchitis Vaccine, Live, I.P.

Nobilis® IB 4-91



sphereon®

Nobilis® IB 4-91 is a live attenuated, freeze-dried vaccine against Infectious Bronchitis serotype 4-91 of chicken.

Composition:

Each freeze-dried pellet contains:

Live attenuated Avian Infectious Bronchitis Virus variant strain 4-91-minimum 3.6 and maximum 5.6 Log₁₀ EID₅₀ per dose
Sorbitol -66.6 mg
Hydrolysed gelatin -33.3 mg
Pancreatic digest of casein-33.3 mg
Disodium phosphate dihydrate-0.167 mg
Water for Injection to 1.0 ml

Target species

Chickens

Indications for use, specifying the target species

For active immunization of chicken to reduce the respiratory signs of infectious bronchitis caused by the variant strain IB 4-91.

Contraindications

None.

Posology and method of administration

At least log₁₀ 3.6 EID₅₀ (1 dose) per animal by either spray vaccination, drinking water or intranasal/intraocular administration.

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 by the intranasal/ocular route.

The vaccine is delivered as a freeze-dried spheres in cups.

The cups may contain 3 up to 100 spheres depending on the required dosages and production yields. In case of the product presented in cups, do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Each container should be used immediately and completely after opening.

Guideline

Broiler: 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.

Future layers and breeders: The vaccine can be administered to future layers and breeders from day old onwards via intranasal/ocular route or coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.

Spray method: The vaccine should be preferably dissolved in distilled water or alternatively in cool, clean water. Where the number of birds is between the standard dosages, the next higher dosage should be used. The contents of cups can be added to 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 per 1 000 doses is suggested.

The vaccine suspension should be spread evenly over the correct number of birds, at a distance of 30-40 cm using a coarse spray, preferably when the birds 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 content of the cup(s) should be poured into the water. Mix the water containing the vaccine well before use. After reconstitution the suspension looks clear.

Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1,000 doses in one litre per age in days up to a maximum volume of 20 litres per 1,000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 40 litres per 1,000 doses. By adding approximately 2 grams of skimmed milk powder or 20 ml of 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 the 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 1 000 doses, 75 ml per 2 500 doses) and administer by means of a standardized dropper. One drop should be applied onto one nostril or one eye. The handler should ensure that the nasal drop is inhaled before freeing the bird.

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

Guideline when the product is used with Nobilis IB Ma5:

The instructions on reconstitution of both lyophilisates and the subsequent application are to be followed as outlined above for spray and intranasal/ocular administration. The same volumes as for the single product should be used.

Special warnings for each target species

Vaccinate healthy animals only.

The vaccine virus may spread from vaccinated to non-vaccinated chickens and appropriate care should be taken to separate vaccinated from non-vaccinated.

Wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

Special precautions for use

Special precautions for use in animals

described for the vaccines administered separately. Simultaneous use of both vaccines increases the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated very low and is minimized by routinely vaccinating all chickens on the premise at the same time and cleaning and disinfection after each production round. Read the product information of Nobilis IB Ma5 before use.

Safety and efficacy data are available which demonstrate that Nobilis IB 4-91 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-IBD. Nobilis IB 4-91 given at day-old can adversely affect the efficacy of turkey rhinotracheitis (TRT) vaccine given within 7 days.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

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. Skimmed milk powder should be added to the drinking water to improve the stability of the vaccine.
- Wash and disinfect hands and equipment after vaccinating.
- The vaccine should be used within 2 hours after reconstitution and should not be stored.
- Do not mix 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 at day-old 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.
- Keep out of reach and sight of children

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. 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.

Care should be taken to avoid spread of the vaccine virus from vaccinated chickens to pheasants.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of spray administration, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product.

Adverse reactions (frequency and seriousness)

In laboratory studies and field trials:

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

In post marketing experience:

In very rare cases mild respiratory signs of disease are reported.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Use during pregnancy, lactation or lay

Nobilis IB4-91 has been shown to be safe in layers and breeders during lay.

Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis IB Ma5 for spray or intranasal/ocular administration to commercial chicks from one day of age onwards. For the mixed products the onset of immunity is 3 weeks and the duration of immunity is 6 weeks for the claimed protection against Massachusetts and variant strain 4-91 of IBV. The safety parameters of the mixed vaccines are not different from those

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Ten times the maximum dose was shown to be safe for the target species by all the recommended routes and methods of administration.

Withdrawal period: Zero days

Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 recommended for use with the veterinary medicinal product.

Storage conditions: Store dark at 2°C-8°C. Do not freeze.

Shelf life in the medical products as packaged for sale

In freeze dried form: at least 24 months

Shelf life after dilution or reconstitution according to the direction

After reconstitution: 2 hours

Nature and contents of the container: The cups are of aluminium foil laminate with a plastic contact layer. The cups are sealed with aluminium foil laminate with a plastic contact layer. Sealed aluminium cups containing 1000 doses

Special precautions for disposal of unused product or waste material, if any:

Dispose waste material by boiling, burning or immersion in a disinfectant approved for use by the appropriate authorities.

