SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91 lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Live attenuated avian infectious bronchitis virus (IBV), variant strain 4-91: ≥ 3.6 $\log_{10}$ EID_{50}*

* EID_{50}: 50% embryo infective dose - the virus titre required to produce infection in 50% of the embryos inoculated.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate:
Vials: off-white/cream-coloured pellet.
Cups: off-white, predominantly sphere shaped.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce the respiratory signs of infectious bronchitis caused by the IBV variant strain 4-91.

Onset of immunity: 3 weeks.
Duration of immunity: 6 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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.

The vaccine virus may spread from vaccinated to non-vaccinated chickens and appropriate care should be taken to separate vaccinated from non-vaccinated chickens.
Wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

Very common (>1 animal / 10 animals treated):	Respiratory signs[1]

[1] May persist for a few days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to

either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Nobilis IB 4-91 has been shown to be safe in layers and breeders during lay.

4.8 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 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.
- 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 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-ILT

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.

4.9 Amount(s) to be administered and administration route

General
Administration of 1 dose per animal by:
- oculonasal use (coarse spray or intranasal/ocular administration); or
- in drinking water use.

The vaccine may be delivered as a freeze-dried cake in a glass vial or as freeze-dried spheres in cups. In case of the latter presentation 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/vaccination scheme

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.

Ocular/intranasal administration or coarse spray gives the best responses, and these should be the methods of choice, especially when vaccinating young chickens.

Drinking water use

The vials should be opened under water or the content of the cup(s) should be poured into the water. In both cases 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 to the drinking water, the vaccine 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.

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 or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear.
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 1,000 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.

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. Ensure that the nasal drop is inhaled before freeing the bird.

Vaccination programme
The veterinarian should determine the optimum vaccination schedule according to the local situation.

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. In-use shelf life after mixing: 2 hours.

4.10 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Aves*, domestic fowl, live viral vaccine, avian infectious bronchitis virus.
ATCvet code: QI01AD07.

Active immunisation against avian infectious bronchitis virus (IBV) variant strain IB 4-91 which causes infectious bronchitis in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Gelatine
Pancreatic digest of casein
Disodium phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product in glass vials as packaged for sale: 9 months.
Shelf life of the veterinary medicinal product in aluminium laminate cups as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Lyophilisate

- Glass vial (type I hydrolytic glass) of 10 ml, with a halogenobutyl rubber bung and sealed with a coded aluminium cap; or
- Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

Pack sizes
Cardboard box with 1 or 10 vial(s) of 500 doses.
Cardboard box with 1 or 10 vial(s) or 10 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 doses.
PET plastic box with 12 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 doses.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5043

9. DATE OF FIRST AUTHORISATION

09 June 1998

10. DATE OF REVISION OF THE TEXT

October 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 23 January 2024

