

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX with 1 vial, 10 vials or 10 cups of lyophilisate
PET PLASTIC BOX with 12 cups of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live attenuated infectious bronchitis virus (IBV) strain 4-91: $\geq 3.6 \log_{10} \text{EID}_{50}^*/\text{dose}$

*EID₅₀: 50% embryo infective dose

3. PACKAGE SIZE

1x 500 doses
1x 1000 doses
1x 2500 doses
1x 5000 doses
1x 10 000 doses
10x 500 doses
10x 1000 doses
10x 2500 doses
10x 5000 doses
10x 10 000 doses
12x 1000 doses
12x 2500 doses
12x 5000 doses
12x 10000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oculonasal suspension / use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5043

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
LABEL – Lyophilisate VIALS (10 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91



2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 doses
1000 doses
2500 doses
5000 doses
10 000 doses

$\geq 3.6 \log_{10}$ EID₅₀ IBV 4-91/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

For ocular suspension or use in drinking water.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
LABEL – Lyophilisate CUPS**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91



**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE
SUBSTANCES**

1000 doses (3-100 spheres)
2500 doses (3-100 spheres)
5000 doses (3-100 spheres)
10000 doses (3-100 spheres)

Live IBV, 4-91

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:

Live attenuated infectious bronchitis virus (IBV) variant strain 4-91: $\geq 3.6 \log_{10} \text{EID}_{50}^*$ per dose

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

Lyophilisate:

Vials: off-white/cream-coloured pellet.

Cups: off-white, predominantly sphere shaped.

3. TARGET SPECIES

Chickens.

4. INDICATIONS FOR USE

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

Onset of immunity: 3 weeks.

Duration of immunity: 6 weeks.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

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.

Laying birds:

Nobilis IB 4-91 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 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.

Overdose:

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

Special restrictions for use and special conditions for use:

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

Major incompatibilities:

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

7. ADVERSE EVENTS

Chickens:

Very common (>1 animal / 10 animals treated):	Respiratory signs ^{1,2}
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¹ May persist for a few days

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

General

At least 3.6 log₁₀ EID₅₀ (1 dose) per animal by:

- oculonasal use (coarse spray or intranasal/ocular administration)
- or in drinking water use.

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

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 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 the 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.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5043

Pack size:

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

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

16. CONTACT DETAILS

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

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

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

Approved 23 January 2024

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date.