1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Ma5 lyophilisate for oculonasal suspension / use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:
Active substance:
Live avian infectious bronchitis virus (IBV), strain Ma5 $\geq 10^{3.5}$ EID50*
*EID50 = 50 % Embryonic Infective Dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sorbitol
Hydrolysed gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate
Solvent:
Patent Blue V (E131)
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Disodium edetate dihydrate
Sodium chloride
Water for injections

Lyophilisate:
Vials: off-white/cream-coloured pellet.
Cups: off-white predominantly sphere shaped.
Solvent (Solvent Oculo/Nasal): blue-coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

To reduce mortality and clinical signs of Massachusetts or serologically related types of infectious bronchitis. A single vaccination gives protective immunity that lasts at least through the normal broiler rearing period (5 – 7 weeks). Where appropriate, e.g. in layers and breeders, revaccination at approximately 6 week intervals is advised.

Onset of immunity: 3 weeks for mixed product use.

Duration of immunity: 6 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The vaccine virus may spread from vaccinates to non-vaccinated birds and appropriate care should be taken to separate vaccinates from non-vaccinates.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands after use.
When spraying the vaccine, to avoid hay-fever like reactions in some individuals, personal protective equipment consisting of respiratory and eye protection should be worn when handling the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory signs[1].

[1] Mild. May occur from 1 to 3 weeks after vaccination.

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.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay.
Emergency vaccination during lay may result in a transient drop in egg production.

3.8 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 4-91 or Nobilis IB Primo QX by spray or intranasal/ocular administration in commercial chicks from one day of age onwards.
For mixed product use, the onset of immunity is 3 weeks.
For mixed use with Nobilis IB 4-91, the duration of immunity is 6 weeks for the claimed protection against Massachusetts and variant strain 4-91 of IBV.
For mixed use with Nobilis IB Primo QX, the duration of immunity is 8 weeks for the claimed protection against Massachusetts and QX-like strains of IBV.
The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately.

Safety and efficacy data are available which demonstrate that Nobilis IB Ma5 (or Nobilis IB Ma5 mixed with Nobilis IB 4-91) can be administered on the same day, but not mixed, to day-old chicks that are vaccinated either by the subcutaneous route, or to day-old chicks that have been vaccinated by the *in ovo* route, with Innovax-ND-IBD.

For the non-mixed associated use of Innovax-ND-IBD with Nobilis IB Ma5 mixed with Nobilis IB 4- 91, the duration of immunity is 6 weeks for the claimed protection against Massachusetts serotypes

and variant strain 4-91 of IBV.

Safety and efficacy data are available which demonstrate that this vaccine can be administered to day-old chicks which are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-ILT.

Simultaneous use of two vaccines increases the risk of recombination of viruses and potential emergence of new variants. However, the chance of a hazard occurring has been estimated as very low and is minimized by routinely vaccinating all chickens on the premises at the same time and cleaning and disinfection after each production cycle.

Read the product information of Nobilis IB 4-91, Nobilis IB Primo QX, Innovax-ND-IBD or Innovax- ND-ILT before use.

Safety and efficacy data are also available which demonstrate that this vaccine can be used concurrently with Nobilis ND Clone 30 Live which should be given at the same time and by the same route as Nobilis IB Ma5. There are no safety or efficacy data concerning the use of Nobilis ND Clone 30 Live when administered concurrently with Nobilis IB Ma5, if Nobilis IB Ma5 has been administered in associated use with the other vaccines mentioned above (Nobilis IB 4-91, Nobilis IB Primo QX, Innovax-ND-IBD or Innovax-ND-ILT).

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

3.9 Administration routes and dosage

At least $10^{3.5}$ EID50 per animal by:
-spray administration
-drinking water administration
- intranasal/intraocular administration

The vaccine may be presented as a freeze-dried pellet in a vial or as freeze-dried spheres in cups.
Cups may contain 3 to 100 spheres depending on the presentation (number of doses) and production yields.

For product presented in cups, the vaccine should not be used if the contents are brownish and/or adhere to the container as this indicates the integrity of the container has been breached.
Each container should be used immediately and completely after opening.

Use the appropriate number of vials or cups for the number of doses

required.

The vaccine may be administered by spray, in the drinking water, or with a dropper into the eye or nose of chickens from 1 day of age onwards.
The optimum time and method of administration depend on the local situation. Where necessary consult technical staff representing the marketing authorisation holder.

Administration by coarse spray or the oculo/nasal route is the method of choice when vaccinating young birds; fine spray for older birds.

Basic vaccination scheme
Vaccination at day old by coarse spray or oculo/nasal administration.

Re-vaccination scheme (breeders/layers)

Revaccination at approximately 4 – 6 weeks and 10 – 12 weeks of age by spray, oculo/nasal or drinking water administration.
Birds should then be vaccinated with an inactivated IB vaccine before the onset of lay in accordance with the manufacturer's directions.

Spray administration
The vaccine should be reconstituted in cool, clean water which is free of iron and chlorine.
Open the vials under water, or where cups are used, open and pour the spheres into the water.
Mix 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 birds. This will vary according to the age of the birds being vaccinated and the management system. The vaccine medicated water should be spread evenly over the correct number of birds, at a distance of 30 – 40 cm (12 – 16"), 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).

Number of doses	Day old birds nozzle producing coarse droplets	Older birds nozzle producing fine droplets
1,000	0.25 litre	1 litre

(Aerosol generators should be used only when it is known to be safe to the birds.)

Drinking water administration
Reconstitution of vaccine
Measure the correct volume of water for the number of birds to be vaccinated (see below).
Open the vials under water, or where cups are used, open and pour the spheres into the water.
Mix water containing the vaccine well before use. After reconstitution the suspension looks clear.
All containers used should be clean and free from any traces of detergent or disinfectant. Mix thoroughly with a clean stirrer, ensuring that all vials used are emptied. Offer to birds immediately.

Use clean cold water, in which chlorine or metals can neither be tasted nor smelt. Where water sanitisers are used consult technical staff representing the marketing authorisation holder. Chlorine at levels as low as 1 ppm is known to have a detrimental effect on vaccine virus stability, therefore the use of liquid skimmed milk is recommended to prolong the life of the virus. This may be added to the water at the rate of 500 ml (approximately 1 pint) per 10 litres of water. After mixing well, the solution should be allowed to stand for 15 – 30 minutes before adding the vaccine. Only skimmed milk should be used, as the fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

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 per litre per age in days up to a volume of 20 litres per 1,000 doses.
For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litres per 1,000 doses. Where the number of birds is between the standard dosages, the next higher dosage should be used.

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 received the correct dose. Special care should be observed concerning the method of administration. For example, small header tanks may require recharging with medicated water several times during a 1 – 2 hour period.

Nipple drinkers are not appropriate for vaccine administration in chickens less than 3 days of age.

Administration:
Water should be withheld before vaccination.
For recommendations see *Management*
below.
Ensure that all medicated water is consumed within 1 – 2 hours. Turn on mains water when all the vaccine water has been consumed.
Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat.

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 half an 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 food is in the food tracks.
3. Turn the lights down low when the water is turned off. For bell drinkers, go round the house emptying and cleaning the drinkers during the half-hour lights low period. Mix up the vaccine according to the recommendations, and towards the end of the half-hour water withholding period, go round 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 food. Therefore, it is important that food is available or the birds will not be interested in drinking. In some cases, it helps to run food 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 half- 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 drinker 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 litres remain below the outlet pipe and you are using 10 litres/1,000 birds to vaccinate, add one extra vial or cup of vaccine when mixing up vaccine for that tank. The use of this extra vaccine is important.
4. 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. Performance should therefore be less adversely affected.

Intranasal/intraocular administration
Dissolve the vaccine in physiological saline solution (usually 30 ml per 1,000 doses)or Solvent Oculo/Nasal and administer by means of a standardised dropper. Mix well before use. After reconstitution the suspension looks clear.
One drop should be applied from a height of a few centimetres into one nostril or one eye. The handler should ensure that the nasal drop is inhaled by the bird.

Guideline when the product is used with Nobilis IB 4-91 or Nobilis IB Primo QX
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 productshould be used.
For the intranasal/ocular mixed use with Nobilis IB Primo QX (1,000 doses only), the Solvent Oculo/Nasal should be used. Read the product information of Nobilis IB Primo QX before use. In-use shelf life after mixing: 2 hours.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse effects other than those indicated in 3.6 are observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI01AD07

To stimulate active immunity against the Massachusetts or serologically related types of infectious bronchitis.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except Nobilis ND Clone 30 Live, Nobilis IB Primo QX or Nobilis IB 4-91 or Solvent Oculo/Nasal recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life of the solvent as packaged for sale: 4 years.
Shelf-life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

Solvent:
Store below 25°C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Lyophilisate in vials: glass vial (glass type III (Ph.Eur)) closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.
Lyophilisate in cups: sealed aluminium laminate cups with a polypropylene (cups) and polypropylene/polyethylene (lids) contact layer.

Solvent: polyethylene vials closed with a halogenobutyl rubber stopper and sealed with a colour coded cap.

Pack sizes:

Cardboard box with 1 or 10 vial(s) containing 1,000, 2,500, 5,000 or 10,000 doses .
Cardboard box with 10 cups containing 1,000, 2,500, 5,000 or 10,000 doses.

PET plastic box with 12 cups containing 1,000, 2,500, 5,000 or 10,000 doses.

Cardboard box with 1 or 10 vials of solvent (35 ml).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/136/001

8. DATE OF FIRST AUTHORISATION

19/02/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/09/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).