SUMMARY OF PRODUCT CHARACTERISTICS

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:
Avian infectious bronchitis virus (IBV), strain Ma5, Live: $\geq 3.5 \log_{10} EID_{50}$*

* EID_{50}: 50% Embryo Infective Dose

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate
Water for injection

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For the induction of active immunity of chickens, from one day-old onwards, to protect against infectious bronchitis caused by Infectious Bronchitis Virus serotype Massachusetts.
The vaccine can be used for primary as well as secondary vaccination.

Onset of immunity: at latest 3 weeks (based upon vaccination-challenge interval tested; this period may be shorter, but this has not been investigated).
Duration of immunity: at least 6 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine virus may spread to unvaccinated birds.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The duration and intensity of the vaccination reaction and the establishment of a solid immunity are dependent on the possible presence of maternal antibodies and on the general health and condition of the birds. Hygiene and management play an essential part in the post-vaccination period.
Sick or weak birds will not develop adequate immunity following vaccination.

Antibiotic medication: When stock is known to be infected with mycoplasma or there is a history of other infections, e.g. *E. coli*, it is suggested that antibiotics are administered to reduce the level of infection. The antibiotic manufacturers' recommendations should be followed at all times.

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, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

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 well-fitting masks to appropriate EU standards or better and eye protection to appropriate EU standards must be worn by the operator and staff.

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

3.6 Adverse events

Chickens:

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

[1] Mild, transient, lasting a few days, depending on the health and condition of the birds.

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 its local representative 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:
Can be used during lay.

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

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 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.

For the 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 the 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. 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 very low and is minimized by routinely vaccinating all chickens on the premises at the same time and cleaning and disinfection after each production round.

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, 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.

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 available which demonstrate that this vaccine can be administered on the same day but not mixed with the live Newcastle disease (strain Clone 30 and C2) vaccines and live rhinotracheitis (strain 11/94) vaccines by the marketing authorisation holder.

Safety and efficacy data are available which demonstrate that Infectious bursal disease vaccine (strain D78) can be administered 7 days after the administration of Nobilis IB Ma5.

If this is not possible, vaccines which target non respiratory diseases such as Marek's disease vaccines may be administered with Nobilis IB Ma5 provided that each of the vaccines is administered using the recommended route and the recommended doses.

No information is available on the safety and efficacy of Nobilis IB Ma5 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 3.5 $\log_{10}$ EID_{50} per animal by
- spray vaccination
- drinking water application
- intranasal/intraocular application

Vaccination programme
The optimal time and method of administration depend largely upon the local situation.
The vaccine is safe to use from 1 day of age onwards.

Guideline
The vaccine can be administered to 1-day old chicks and older chickens by coarse spray or by the intranasal/ocular route of administration. The vaccine can be administered to 7-day and older chicks by drinking water. If prolonged immunity is required, e.g. the chickens can be revaccinated every 6 weeks.

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:
When administering the vaccine by drinking water use cool, clean water supplemented with 2 grams of skimmed milk powder or 50 ml of liquid skimmed milk per litre to dissolve the vaccine, as it is known that this will make the virus retain its activity.

Reconstitution of vaccine:
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. The vaccine is presented in vials under vacuum. Measure the correct volume of water for the number of birds to be vaccinated (see below) and open the correct number of vials of vaccine under the surface of the water. 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 smelled. Where water sanitisers are used consult the marketing authorisation holders technical staff. 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.
After reconstitution the suspension looks clear.

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.

Administration

Water should be withheld before vaccination. For recommendations see below under “Management”. 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 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.

Spray vaccination of day old chicks

This technique has been developed for use in day-old birds and is normally required for emergency use only. Only spray apparatus approved by the marketing authorisation holder should be used and it is advisable to consult the technical staff of the distributors before using this technique.

Oculo-nasal administration:

Reconstitute the vaccine with the appropriate amount of a suitable diluent and administer by means of the standardised dropper. One drop should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird. For eye- or nose-drop administration the solvent Nobilis Diluent Oculo Nasal, is available in a dropper in two dosage forms (1 000 and 2 500 doses).

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 product should be used.
For the intranasal/ocular mixed use with Nobilis IB Primo QX, the Solvent Oculo/Nasal (1 000 doses only) 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)

Following the administration of a 100-1 000 fold the minimally guaranteed dose, no adverse events other than the ones described under section 3.6 have been 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 strain of Avian Infectious Bronchitis Virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis IB 4-91 or Nobilis IB Primo QX 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 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.

5.4 Nature and composition of immediate packaging

Lyophilisate in vials: 1 or 10 vials of hydrolytic type II or type I glass containing the freeze-dried pellet. The vial is closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap containing 500, 1 000, 2 500, 5 000 or 10 000 doses.

Lyophilisate in cups: Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer containing 1 000, 2 500, 5 000 or 10 000 doses.

Pack sizes:
Cardboard box with 1 or 10 glass vial(s) containing 500, 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.
Not all pack sizes may be marketed.

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

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

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4139

8. DATE OF FIRST AUTHORISATION

25 October 2005

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 23 March 2026