

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

**CARDBOARD BOX (vials) or (CUPS)
PET PLASTIC BOX (CUPS)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Content per dose: $\geq 3.5 \log_{10}$ EID₅₀ live avian infectious bronchitis virus strain IB Ma5.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension / use in drinking water

4. PACKAGE SIZE

500 doses
1,000 doses
2,500 doses
5,000 doses
10,000 doses
10 x 500 doses
10 x 1,000 doses
10 x 2,500 doses
10 x 5,000 doses
10 x 10,000 doses
12 x 1000 doses
12 x 2500 doses
12 x 5000 doses
12 x 10000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral or oculonasal administration for chickens.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: {month/year}
Once reconstituted, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.
Keep the vial in the outer carton.

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

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 2

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4283

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Infectious bronchitis vaccine for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose contains: $\geq 3.5 \log_{10}$ EID₅₀ live IB Ma5 virus

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

500 doses

1,000 doses

2,500 doses

5,000 doses

10,000 doses

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Vm 01708/4283

POM-VPS

Store in a refrigerator.

Once reconstituted, use within 2 hours. Keep the vial in the outer carton.

Read package leaflet before use.

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (cups)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Live avian infectious bronchitis virus strain
IB Ma5 $\geq 3.5 \log_{10}$ EID₅₀* per dose.
EID₅₀ = 50% embryonic infective dose.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension / use in drinking water

4. PACKAGE SIZE

10 x 1,000 doses
10 x 2,500 doses
10 x 5,000 doses
10 x 10,000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

To reduce mortality and clinical signs of Massachusetts or serologically related types of infectious bronchitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spray, in drinking water or oculonasal administration. For dosage and detailed administration advice:
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Precautions, warnings and disposal advice:

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once reconstituted, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4283

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live IBV, Ma5; for chickens

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses (3–100 spheres)
2,500 doses (3–100 spheres)
5,000 doses (3–100 spheres)
10,000 doses (3–100 spheres)

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Vm 01708/4283
POM-VPS
MSD Animal Health UK Ltd.

PACKAGE LEAFLET:
Nobilis IB Ma5

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

After reconstitution, one dose contains:

Live avian infectious bronchitis virus strain
IB Ma5 $\geq 3.5 \log_{10}$ EID₅₀

4. INDICATION(S)

Induction of active immunity of chickens, from one day-old onwards, to protect against infectious bronchitis caused by infectious bronchitis virus serotype Massachusetts. 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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.

Sick or weak birds will not develop adequate immunity following vaccination.

6. ADVERSE REACTIONS

Vaccination may induce a mild transient respiratory reaction lasting a few days, which may depend on the health and condition of the birds. After administration no symptoms other than the ones described above expected.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Can be used during lay.

Drinking water:

When administering the vaccine by drinking water use cool, clean water supplemented with 2 gram of skimmed milk powder or 50ml 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 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 400 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.

Vaccine in vials is presented 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 MSD 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.

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.

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 MSD Animal Health UK Ltd should be used and it is advisable to consult the technical staff of the distributors before using this technique.

Oculonasal 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 Nobilis Diluent Oculo Nasal, is available in a dropper in two dosage forms (1,000 and 2,500 doses).

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.

Vaccination programme:

The optimal time and method of administration depend largely upon the local situation. 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.

In-use shelf life after mixing: 2 hours.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

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

Keep the container in the outer carton.

Do not use after the expiry date stated on the label and carton.

Keep out of the sight and reach of children.

Shelf life after reconstitution: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The vaccine virus may spread to unvaccinated birds.

Special precautions for use in animals:

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.

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

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 premise at the same time and cleaning and disinfection after each production round. 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-IBD.

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 MSD. 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 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.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except Nobilis IB 4-91, Nobilis IB Primo QX or Innovax-ND-IBD recommended for use with the veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2022

15. OTHER INFORMATION

ATCvet code: QI01AD07

Pharmacotherapeutic group: Immunologicals for Aves, live viral vaccine for domestic fowl.

To stimulate active immunity against the Massachusetts strain of avian infectious bronchitis virus.

For animal treatment only.

Pack sizes:

Cardboard box with 1 or 10 vials of hydrolytical 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 dose, 1,000 doses, 2,500 doses, 5,000 doses or 10,000 doses.

Sealed aluminium laminate cup containing 1,000; 2,500; 5,000 or 10,000 doses.

PET plastic box with 12 cups of 1,000 doses

PET plastic box with 12 cups of 2,500 doses

PET plastic box with 12 cups of 5,000 doses

PET plastic box with 12 cups of 10,000 doses

Not all presentations may be marketed.

MA number:

Vm 01708/4283

Legal category:

POM-VPS

To be supplied only on veterinary prescription.

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Approved 28 December 2022

