PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with 10 cups of lyophilizate
PET PLASTIC BOX 12 cups of lyophilizate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX lyophilisate for oculonasal suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Avian infectious bronchitis virus (IBV), type QX, strain D388, live: $10^{4.0}$ – $10^{5.5}$ EID_{50}*/dose

*EID_{50}: 50% egg infective dose **3. PACKAGE SIZE**

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

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Ocunasal use (coarse spray or oculonasal administration).

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 01708/5042

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX with 10 vials of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent Oculo/Nasal for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PACKAGE SIZE

10x 35 ml

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Read the vaccine package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Do not freeze.

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 01708/5042

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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
Lyophilisate cups

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 doses (3-100 spheres)

2 500 doses (3-100 spheres)
5 000 doses (3-100 spheres)
10 000 doses (3-400 spheres)

Live IBV, D388

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 IMMEDIATE LABEL OF THE SOLVENT
LABEL - Solvent VIALS

1. NAME OF THE SOLVENT

Solvent Oculo/Nasal

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

35 ml

3. ROUTES OF ADMINISTRATION

Read the vaccine package before use.

4. STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

5. BATCH NUMBER

Lot

6. EXPIRY DATE

Exp.

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX lyophilisate and solvent for oculonasal suspension for chickens
Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

2. COMPOSITION

Each dose of reconstituted vaccine contains:

Active substances:
Avian infectious bronchitis virus (IBV), type QX, strain D388 live:, $10^{4.0}$ – $10^{5.5}$ EID_{50}[1]

[1] EID_{50}: 50% egg infective dose - the virus titre required to produce infection in 50% of the eggs inoculated.

Lyophilisate: Off white, predominantly sphere shaped.
Solvent (Solvent Oculo/Nasal): blue-coloured solution.

3. TARGET SPECIES

Chickens.

4. INDICATIONS FOR USE

For active immunisation of chickens in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV).

Onset of immunity: 3 weeks.
Duration of immunity: 8 weeks.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:

The vaccine virus is capable of spreading to in contact birds for a minimum of 20 days after vaccination and appropriate care should be taken to separate vaccinated from non-vaccinated chickens. During this time, the contact of immunosuppressed

and unvaccinated chickens with vaccinated chickens should be avoided. Precautionary measures should be taken to prevent spreading to wildlife. The premises must be cleaned and disinfected after each production round.

This vaccine should only be used after it has been established that the QX-like IBV variant strain is epidemiologically relevant. It is important to avoid introduction of the IB D388/QX vaccine virus into premises in which the wild type strain is not present. The IB D388/QX vaccine should only be applied in hatcheries to chickens from 1 day of age or older if adequate controls are in place to avoid the spread of the vaccine virus to birds that will be transported to non-IB QX exposed flocks.
The vaccine has been demonstrated to provide protection against QX-like variant. The protection against other circulating IB strains has not been investigated.
All chickens on the site should be vaccinated at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of coarse spray, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product. Wash and disinfect hands and equipment after vaccination to avoid the spread of the virus.

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

Laying birds:
The safety of Nobilis IB Primo QX has been demonstrated when administered during lay. The efficacy of Nobilis IB Primo QX has not been demonstrated when administered during lay.
A decision to use this vaccine during lay should be made on a case by case basis.

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 oculonasal application. 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. For the mixed products the onset of immunity is 3 weeks and 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. Read the package leaflet of Nobilis IB Ma5 before use.

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

Overdose:
Very mild inflammatory changes have occasionally been found in the kidneys of specific pathogen free (SPF) chickens after administration of a 10-fold overdose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 or Solvent Oculo/Nasal recommended for use with the veterinary medicinal product.

7. ADVERSE EVENTS

Chickens:

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

[1] Mild transient respiratory reaction that may occur for at least 10 days after vaccination.

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 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, ROUTES AND METHOD OF ADMINISTRATION

After reconstitution, administer 1 dose of vaccine by coarse spray or by the oculonasal route of administration to chickens from 1 day of age or older.

9. ADVICE ON CORRECT ADMINISTRATION

Cups may contain 3 spheres to up to 400 spheres depending on the required dosages and production yields. 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. Reconstitute the lyophilisate immediately and entirely after opening of the cup.

Administration routes:

Coarse spray:
When spray devices are used it is advisable to consult the technical staff of the distributors before using this technique. Apply coarse spray ≥250 micrometer. All containers used for reconstitution should be clean and free from any traces of detergent or disinfectant.

1) Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water for the number of birds to be vaccinated (depends on devices used).
2) Add the contents of the correct number of cups while stirring.
3) Mix thoroughly with a clean stirrer, ensuring that all vaccine is dissolved. After reconstitution the suspension looks clear.
4) Spray on birds immediately.

Oculonasal use:
Solvent Oculo/Nasal should be usedor oculonasal application.
1) The contents of a cup (1,000 doses only) can be added to Solvent Oculo/Nasal using the included adapter and administered after connecting the included dropper.
2) Shake the vaccine suspension. After reconstitution the suspension looks clear.
3) One drop containing one dose should be applied into 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.
Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.
Solvent: Store below 25 °C. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

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 01708/5042

Pack sizes:

Cardboard box with 10 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 doses.
Cardboard box with 10 cups of 1000 doses + cardboard box with 10 x 35 ml vial of solvent supplemented with dropper and adapter.
PET plastic box with 12 cups of 1000 doses, 2500 doses or 5000 doses.
PET plastic box with 6 cups of 10 000 doses.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ
United Kingdom

Manufacturer responsible for the 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

Nobilis IB Primo QX is intended to protect chickens against clinical signs of disease caused by IBV variant strain D388 only and should not be used as a replacement for

other IBV vaccines. Chickens should be vaccinated against other prevalent IBV serotypes (e.g. Massachusetts) according to the local IB vaccination programme.

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only.

Gavin Hall
Approved: 02 September 2024