ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Live attenuated avian infectious bronchitis virus, strain D388: $10^{4.0} – 10^{5.5}$ EID_{50}[1]

[1] 50% egg infective dose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for oculonasal suspension
Lyophilisate for oculonasal suspension.

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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. 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 vaccine virus into premises in which the wild type strain is not present. The IB D388 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.

4.5 Special precautions for use

Special precautions for use in animals

All chickens on the site should be vaccinated at the same time.

Vaccinated chickens may excrete the vaccine strain up to 20 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

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.

4.6 Adverse reactions (frequency and seriousness)

A mild transient respiratory reaction (including nasal exudates) may very rarely occur for at least 10 days after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 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 product information 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.

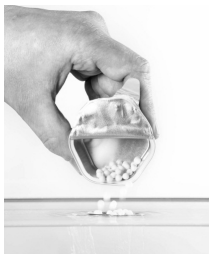
4.9 Amounts to be administered and administration route

Administer 1 dose of reconstituted vaccine by coarse spray or by oculonasal route to chickens from 1 day of age or older. 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.

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 microns. 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) Offer to birds immediately.



Oculonasal use:
Solvent Oculo/Nasal should be used for 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccine.
ATCvet code: QI01AD07.

To stimulate active immunity against the D388/QX type of avian infectious bronchitis virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate

Solvent:
Patent Blue V (E131)
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Disodium edetate dihydrate
Sodium chloride
Sodium hydroxide or hydrochloric acid (for pH adjustment)
Water for injections

6.2 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.

6.3 Shelf life

Shelf life of the lyophilisate as packaged for sale: 24 months.
Shelf life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

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

6.5 Nature and composition of immediate packaging

Lyophilisate:
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.

Solvent (Solvent Oculo/Nasal):
Low density polyethylene (LDPE) vial of 35 ml with a halogenobutyl rubber stopper and aluminium cap.

Packaging:
Cardboard box with 10 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (2,500 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (5,000 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (10,000 doses per 61 mm diameter cup (3-400 spheres)).
Cardboard box with 10 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres)) + cardboard box with 10 x 35 ml vial of solvent supplemented with dropper and adapter.
PET plastic box with 12 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres))
PET plastic box with 12 cups of lyophilisate (2,500 doses per 42 mm diameter cup (3-100 spheres))
PET plastic box with 12 cups of lyophilisate (5,000 doses per 42 mm diameter cup (3-100 spheres))
PET plastic box with 6 cups of lyophilisate (10,000 doses per 61 mm diameter cup (3-400 spheres)).

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/174/001–009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04/09/2014.
Date of last renewal: 13/06/2019.

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

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

Merck Sharp & Dohme Animal Health, S.L.
C/ Zeppelin, 6. Pol. Ind. El Montalvo I,
Parcela 38, Carbajosa de la Sagrada,
Salamanca, 37008,
Spain

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with 10 cups of lyophilisate
PET PLASTIC BOX with 12 cups of lyophilisate
PET PLASTIC BOX with 6 cups of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated avian infectious bronchitis virus, strain D388: $10^{4.0} – 10^{5.5}$ EID_{50}/dose

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension

4. 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

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Spray or oculonasal administration.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
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

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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/174/001 (10 x 1,000 doses)
EU/2/14/174/002 (10 x 1,000 doses + 10 x 35 ml solvent)
EU/2/14/174/003 (10 x 5,000 doses)
EU/2/14/174/004 (10 x 10,000 doses)
EU/2/14/174/005 (10 x 2,500 doses)
EU/2/14/174/006 (12 x 1,000 doses)
EU/2/14/174/007 (12 x 2,500 doses)
EU/2/14/174/008 (12 x 5,000 doses)
EU/2/14/174/009 (6 x 10,000 doses)

17. MANUFACTURER'S BATCH NUMBER

Lot

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 SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for oculonasal suspension.

4. PACKAGE SIZE

10x 35 ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the vaccine package leaflet before use.
Oculonasal use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

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

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

For animal treatment only.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/174/002

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL - Lyophilisate CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB Primo QX 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live IBV, D388

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 (3-400 spheres)

4. ROUTE(S) OF ADMINISTRATION

See package leaflet.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

LABEL - Solvent VIALS

1. NAME OF THE VETERINARY PRODUCT

Solvent Oculo/Nasal

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

35 ml

3. ROUTE 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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Nobilis IB Primo QX lyophilisate and solvent for oculonasal suspension for chickens
Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

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

Marketing authorisation holder and 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 Primo QX lyophilisate and solvent for oculonasal suspension for chickens
Nobilis IB Primo QX lyophilisate for oculonasal suspension for chickens

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

Each dose of reconstituted vaccine contains:
Live attenuated avian infectious bronchitis virus, strain D388: $10^{4.0} – 10^{5.5}$ EID_{50}[1]

[1] 50% egg infective dose.

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

4. INDICATION(S)

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. ADVERSE REACTIONS

A mild transient respiratory reaction (including nasal exudates) may very rarely occur for at least 10 days after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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. 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.

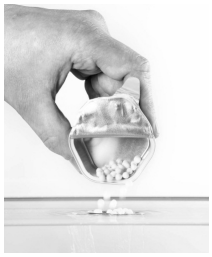
9. ADVICE ON CORRECT ADMINISTRATION

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 microns. 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) Offer to birds immediately.



Oculonasal use:
Solvent Oculo/Nasal is available as solvent for 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 PERIOD(S)

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.
Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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. 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.

Special precautions for use in animals:
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.

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

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.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. 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.

Packaging:
Cardboard box with 10 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (2,500 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (5,000 doses per 42 mm diameter cup (3-100 spheres)).
Cardboard box with 10 cups of lyophilisate (10,000 doses per 61 mm diameter cup (3-400 spheres)).
Cardboard box with 10 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres)) + Cardboard box with 10 x 35 ml vial of solvent supplemented with dropper and adapter.
PET plastic box with 12 cups of lyophilisate (1,000 doses per 42 mm diameter cup (3-100 spheres)).
PET plastic box with 12 cups of lyophilisate (2,500 doses per 42 mm diameter cup (3-100 spheres)).
PET plastic box with 12 cups of lyophilisate (5,000 doses per 42 mm diameter cup (3-100 spheres)).
PET plastic box with 6 cups of lyophilisate (10,000 doses per 61 mm diameter cup (3-400 spheres)).

Not all pack sizes may be marketed.