ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91 lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance
Live attenuated avian infectious bronchitis virus (IBV), variant strain 4-91: ≥ 3.6 $\log_{10}$ EID_{50}*

* EID_{50}: 50% embryo infective dose - the virus titre required to produce infection in 50% of the embryos inoculated.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce the respiratory signs of infectious bronchitis caused by the variant strain IB 4-91.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

The vaccine virus may spread from vaccinated to non-vaccinated chickens and appropriate care should be taken to separate vaccinated from non-vaccinated.
Wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

4.5 Special precautions for use

Special precautions for use in animals
Nobilis IB 4-91 is intended to protect chickens against respiratory signs of disease caused by IBV variant strain 4-91 only and should not be used as a replacement for other IBV vaccines. The product should only be used after it has been established that IBV variant strain 4-91 is epidemiologically relevant in the area. Care should be taken to avoid the introduction of the variant strain into an area where it is not present.

Care should be taken to avoid spread of the vaccine virus from vaccinated chickens to pheasants.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of spray administration, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies and field trails:
Vaccination with Nobilis IB 4-91 may very commonly induce mild respiratory signs of disease which may persist for a few days depending on the health and condition of the chickens.

In post marketing experience:
In very rare cases mild respiratory signs of disease are reported.

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

Nobilis IB4-91 has been shown to be safe in layers and breeders during lay.

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 intranasal/ocular administration to commercial chicks from one day of age onwards. For the mixed products the onset of immunity is 3 weeks and the duration of immunity is 6 weeks for the claimed protection against Massachusetts and variant strain 4-91 of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. 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 and is minimized by routinely vaccinating all chickens on the premise at the same time and cleaning and disinfection after each production round. Read the product information of Nobilis IB Ma5 before use.

Nobilis IB 4-91 given at day-old can adversely affect the efficacy of turkey rhinotracheitis (TRT) vaccine given within 7 days.

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

Coarse spray, oculonasal or in drinking water use.

At least 3.6 $\log_{10}$ EID_{50} (1 dose) per animal by coarse spray, drinking water or intranasal/ocular administration. Where the number of chickens is between the standard dosages, the next higher dosage should be used.
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.

Guideline
Broiler: The vaccine can be administered to 1-day-old chicks and older chickens by coarse spray or by intranasal/ocular administration. The vaccine can be administered to 7-day and older chickens by drinking water.
Future layers and breeders: The vaccine can be administered to future layers and breeders from day old onwards via intranasal/ocular route or coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.

Spray method
The vaccine should preferably be dissolved in distilled water or alternatively in cool, clean water. The appropriate number of 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.
The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the chickens. This will vary according to the age of the chickens being vaccinated and the management system, but 250 to 400 ml of water per 1,000 doses is suggested. The vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30–40 cm using a coarse spray, preferably when the chickens 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.

Drinking water
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.
Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1,000 doses in one litre per age in days up to a maximum volume of 20 litres per 1,000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 40 litres per 1,000 doses. By adding approximately 2 grams of skimmed milk powder or 20 ml of liquid skimmed milk per litre of water the virus retains its activity longer.
Ensure that all the vaccine suspension is consumed within 1–2 hours. The vaccine should be given in the early morning as this is the main period of water intake or during the cool period on a hot day. Feed should be available when vaccinating. Water should be withheld before vaccination to make the chickens thirsty. The length of time of water deprivation is strongly dependent on the climatological circumstances. Water withholding should be kept as short as possible with a minimum of half an hour. A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergents and disinfectants.
Turn on mains water when all the vaccine water has been consumed.

Intranasal/ocular administration
Dissolve the vaccine in physiological saline solution or sterile distilled water (usually 30 ml per 1,000 doses, 75 ml per 2,500 doses) and administer by means of a standardized dropper. One drop should be applied onto one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Ocular/intranasal administration or coarse spray gives the best responses and these should be the methods of choice, especially when vaccinating young chickens.

Vaccination programme
The veterinarian should determine the optimum vaccination schedule according to the local situation.

Guideline when the product is used with Nobilis IB Ma5

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.

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

Ten times the maximum dose was shown to be safe for the target species by all the recommended routes and methods of administration.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

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

Active immunisation against avian infectious bronchitis virus variant strain IB 4-91 which causes infectious bronchitis in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Gelatine
Pancreatic digest of casein
Disodium phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 recommended for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product in glass vials as packaged for sale: 9 months.
Shelf life of the veterinary medicinal product in aluminium laminate cups as packaged for sale: 24 months.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate
Glass vial (type I hydrolytic glass) of 10 ml containing 500; 1,000; 2,500; 5,000 or 10,000 doses closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.

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.

Packaging
Cardboard box with 1 or 10 vials of 500 doses.
Cardboard box with 1 or 10 vials of 1,000 doses.
Cardboard box with 1 or 10 vials of 2,500 doses.
Cardboard box with 1 or 10 vials of 5,000 doses.
Cardboard box with 1 or 10 vials of 10,000 doses.
Cardboard box with 10 cups of 1,000 doses.
Cardboard box with 10 cups of 2,500 doses.
Cardboard box with 10 cups of 5,000 doses.
Cardboard box with 10 cups of 10,000 doses.

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 product 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/2/98/006/001-014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09/06/1998.
Date of last renewal: 21/05/2008.

10. DATE OF REVISION OF THE TEXT

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

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

ANNEX II

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

Name and address of the manufacturer of the biological active substance
Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Name and address of the manufacturer responsible for batch release
Intervet International
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 their 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 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

CARTON BOX with 1 vial, 10 vials or 10 cups of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91 lyophilisate for suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated infectious bronchitis virus strain 4-91 ≥ 3.6 $\log_{10}$ EID_{50}* per dose

*EID_{50}: 50% embryo infective dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.
Read the package leaflet before use.

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. SPECIAL 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/2/98/006/001 (1,000 doses, vial)
EU/2/98/006/002 (2,500 doses, vial)
EU/2/98/006/003 (5,000 doses, vial)
EU/2/98/006/004 (10,000 doses, vial)
EU/2/98/006/005 (10x 1,000 doses, vials)
EU/2/98/006/006 (10x 2,500 doses, vials)
EU/2/98/006/007 (10x 5,000 doses, vials)
EU/2/98/006/008 (10x 10,000 doses, vials)
EU/2/98/006/009 (1x 500 doses, vial)

EU/2/98/006/010 (10x 500 doses, vials)
EU/2/98/006/011 (10x 1,000 doses, cups)
EU/2/98/006/012 (10x 5,000 doses, cups)
EU/2/98/006/013 (10x 10,000 doses, cups
EU/2/98/006/014 (10x 2,500 doses, cups)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91

2. QUANTITY OF ACTIVE SUBSTANCE(S)

≥ 3.6 $\log_{10}$ EID_{50} IBV per dose

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

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

4. ROUTE(S) OF ADMINISTRATION

Intranasal/ocular, spray or drinking water

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER.

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91

2. QUANTITY OF ACTIVE SUBSTANCE

Live IBV, 4-91

3. CONTENTS BY WEIGHT, BY VOLUME OR 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

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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Nobilis IB4-91 lyophilisate for suspension for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, 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 4-91 lyophilisate for suspension for chickens

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

Live attenuated infectious bronchitis virus variant strain 4-91: ≥ 3.6 $\log_{10}$ EID_{50}* per dose

* EID_{50}: 50% embryo infective dose - the titre required to infect 50% of the embryos inoculated with the virus.

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

4. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of infectious bronchitis caused by the variant strain IB 4-91.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In laboratory studies and field trails:
Vaccination with Nobilis IB 4-91 may very commonly induce mild respiratory signs of disease which may persist for a few days depending on the health and condition of the chickens.

In post marketing experience:
In very rare cases mild respiratory signs of disease are reported.

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

Coarse spray, oculonasal or in drinking water use.

At least 3.6 $\log_{10}$ EID_{50} (1 dose) per animal by coarse spray, drinking water or intranasal/ocular administration. Where the number of chickens is between the standard dosages, the next higher dosage should be used.

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.

Guideline
Broiler: The vaccine can be administered to 1-day-old chicks and older chickens by coarse spray or by intranasal/ocular administration. The vaccine can be administered to 7-day and older chickens by drinking water.
Future layers and breeders: The vaccine can be administered to future layers and breeders from day old onwards via intranasal/ocular route or coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.

Spray method
The vaccine should preferably be dissolved in distilled water or alternatively in cool, clean water. The appropriate number of vials should be opened under the 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.
The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the chickens. This will vary according to the age of the chickens being vaccinated and the management system, but 250 to 400 ml of water per 1,000 doses is suggested. The vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30–40 cm using a coarse spray, preferably when the chickens 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.

Drinking water
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.
Use cool, clean water to dissolve the vaccine. For administration of the vaccine, as a general rule, dissolve 1,000 doses in one litre per age in days up to a maximum volume of 20 litres per 1,000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 40 litres per 1,000 doses. By adding approximately 2 grams of skimmed milk powder or 20 ml of liquid skimmed milk per litre of water the virus retains its activity longer. Ensure that all the vaccine suspension is consumed within 1–2 hours. The vaccine should be given in the early morning as this is the main period of water intake or during the cool period on a hot day. Feed should be available when vaccinating. Water should be withheld before vaccination to make the chickens thirsty. The length of time of water deprivation is

strongly dependent on the climatological circumstances. Water withholding should be kept as short as possible with a minimum of half an hour. A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergents and disinfectants. Turn on mains water when all the vaccine water has been consumed.

Intranasal/ocular administration
Dissolve the vaccine in physiological saline solution or sterile distilled water (usually 30 ml per 1,000 doses, 75 ml per 2,500 doses) and administer by means of a standardized dropper. One drop should be applied onto one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Ocular/intranasal administration or coarse spray gives the best responses and these should be the methods of choice, especially when vaccinating young chickens.

Vaccination programme
The veterinarian should determine the optimum vaccination schedule according to the local situation.

Guideline when the product is used with Nobilis IB Ma5
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.

9. ADVICE ON CORRECT ADMINISTRATION

Since the stability of IBV in suspension may be low due to sensitivity to high temperatures and impurities, water used for dissolving the freeze-dried vaccine should be cool and of good quality. By adding skimmed milk to the drinking water the vaccine virus retains its activity longer. Only skimmed milk should be used, since fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date 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 may spread from vaccinated to non-vaccinated chickens and appropriate care should be taken to separate vaccinated from non-vaccinated.
Wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

Special precautions for use in animals:
Nobilis IB 4-91 is intended to protect chickens against respiratory signs of disease caused by IBV variant strain 4-91 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.
The product should only be used after it has been established that IBV variant strain 4-91 is epidemiologically relevant in the area. Care should be taken to avoid the introduction of the variant strain into an area where it is not present.
Care should be taken to avoid spread of the vaccine virus from vaccinated chickens to pheasants.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of spray administration, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product.

Lay:
Nobilis IB4-91 has been shown to be safe in layers and breeders during lay.

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 intranasal/ocular administration to commercial chicks from one day of age onwards. For the mixed products the onset of immunity is 3 weeks and the duration of immunity is 6 weeks for the claimed protection against Massachusetts and variant strain 4-91 of IBV. The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. 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 and is minimized by routinely vaccinating all chickens on the premise at the same time and cleaning and disinfection after each production round. Read the product information of Nobilis IB Ma5 before use.
Nobilis IB 4-91 given at day-old can adversely affect the efficacy of turkey rhinotracheitis (TRT) vaccine given within 7 days.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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):
Ten times the maximum dose was shown to be safe for the target species by all the recommended routes and methods of administration.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except Nobilis IB Ma5 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 INSERT WAS LAST REVISED

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

Active immunisation against avian infectious bronchitis virus variant strain IB 4-91 which causes infectious bronchitis in chickens.

Packaging:
Cardboard box with 1 or 10 vials of 500 doses.
Cardboard box with 1 or 10 vials of 1,000 doses.
Cardboard box with 1 or 10 vials of 2,500 doses.
Cardboard box with 1 or 10 vials of 5,000 doses.
Cardboard box with 1 or 10 vials of 10,000 doses.
Cardboard box with 10 cups of 1,000 doses.
Cardboard box with 10 cups of 2,500 doses.
Cardboard box with 10 cups of 5,000 doses.
Cardboard box with 10 cups of 10,000 doses.

Not all pack sizes may be marketed.