ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains per dose:

2.1 Active substance

Live attenuated avian Infectious Bronchitis Virus (IBV) variant strain 4-91: $\geq 3.6 \log_{10} \text{EID}_{50}$ *

* EID$_{50} = 50\%$ Embryo infective dose: the virus titre required to produce infection in 50\% of the embryos inoculated.

2.2 Excipient(s) knowledge of which is essential for the proper administration of the veterinary medicinal product

None

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PHARMACOLOGICAL PROPERTIES

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

5. CLINICAL PARTICULARS

5.1 Target species

Chickens

5.2 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.

5.3 Contra-indications

The safety and efficacy of the vaccine in future layers and breeders or chickens in lay have not been sufficiently documented therefore the product should not be used in future layers and breeders or chickens in lay.

Nobilis IB 4-91 given at day-old can adversely affect the efficacy of Turkey Rhinotracheitis (TRT) vaccine given within 7 days; therefore this vaccination scheme is contraindicated.

5.4 Undesirable effects (frequency and seriousness)

Vaccination with Nobilis IB 4-91 may induce mild respiratory signs of disease which may persist for a few days depending on the health and condition of the chickens.
5.5 Special precautions for use

Only healthy animals should be vaccinated.

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 vaccinates to pheasants.

5.6 Use during pregnancy or lactation

Not applicable.

5.7 Interactions with other medicaments and forms of interaction

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

Do not mix or administer with other products.

5.8 Posology and method of administration

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

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. 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. 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, give 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:**
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. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.

5.9 **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.

5.10 **Special warnings for each target species**

The vaccine virus may spread from vaccinates to non-vaccinated chickens and appropriate care should be taken to separate vaccinates from non-vaccinates.

Wash and disinfect hands and equipment after vaccinating to avoid spread of the virus.

5.11 **Withdrawal periods**

Zero days.

5.12 **Special safety precautions to be taken by persons administering the product to animals**

None

6. **PHARMACEUTICAL PARTICULARS**

6.1 **Incompatibilities (major)**

Viruses are sensitive to high temperature and to chlorine and impurities present in the diluent. Use only cool, clean water when given by drinking water or spray. 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.

6.2 **Shelf-life, when necessary after reconstitution of the veterinary medicinal product or when the container is opened for the first time**

In freeze-dried form: 9 months at 2°C to 8°C.

After reconstitution: The vaccine should be used within 2 hours.

6.3 **Special precautions for storage**

Store at 2-8°C. Protect from light. Do not freeze.

6.4 **Nature and contents of the container**

A 10 ml vial of Type II hydrolytic glass containing 1 000, 2 500, 5 000 or 10 000 doses of freeze-dried vaccine. The vial is closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap. The product is presented as a single vial or in multipacks of 10 vials of the same dosage.
6.5 Special precautions for disposal of unused product or waste material, if any

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

6.6 CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

The import, sale, supply and/or use of Nobilis IB 4-91 is/or may be prohibited in certain Member States on the whole or part of its territory pursuant to National animal health policy. Any person intending to import, sell, supply and/or use Nobilis IB 4-91 has to consult the relevant Member States competent Authorities on the current vaccination policies prior to the import, sale, supply and/or use.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

8. NUMBERS IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT
ANNEX II

THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND CONDITIONS OF THE MARKETING AUTHORISATION
A. MANUFACTURING AUTHORISATION HOLDER

Manufacturer responsible for batch release

Intervet International
Wim de Körverstraat 35,
5831 AN Boxmeer,
The Netherlands

Manufacturing Authorisation issued on 30 May 1995

by

Ministerie van Landbouw, Natuurbeheer en Visserij
The Hague
The Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC Member States prohibit or/ may prohibit the import, sale, supply and/or use of Nobilis IB 4-91 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 programs for the diagnosis, control and 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.

D. STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Not applicable

ANNEX III

LABELLING AND PACKAGE INSERT
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Nobilis IB 4-91.

2. STATEMENT OF ACTIVE SUBSTANCE(S)
Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 \( \geq 3.6 \log_{10} \text{EID}_{50} \). *

* \( \text{EID}_{50} \) = 50% Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM
A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE
10 ml vial of 1000 doses, containing at least 3.6 \( \log_{10} \text{EID}_{50} \) per dose.

5. TARGET SPECIES
Chickens.

6. INDICATION(S)
Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD
Zero days.

9. SPECIAL WARNING(S), IF NECESSARY
The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.
The product should not be used in future layers and breeders or chickens in lay.
Wash and disinfect hands and equipment after vaccinating.
See package insert for additional warnings
10. **EXPIRY DATE**

   {month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

    Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

    For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

    Keep out of reach of children.

15. **NAME AND ADDRESS OF THE MARKETING AUTHORITY AND OF THE MANUFACTURING AUTHORITY RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

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

16. **NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

17. **MANUFACTURER'S BATCH NUMBER**

18. **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

    Veterinary medicinal product subject to prescription
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 $\geq 3.6 \log_{10} \text{EID}_{50}$. *

* $\text{EID}_{50} = 50\%$ Embryo infective dose: the titre required to infect 50\% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE

10 ml vial of 2500 doses, containing at least $3.6 \log_{10} \text{EID}_{50}$ per dose.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings
10. **EXPIRY DATE**

{month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

Keep out of reach of children.

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

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

16. **NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

17. **MANUFACTURER'S BATCH NUMBER**

18. **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription
1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis IB 4-91.

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 \( \geq 3.6 \log_{10} \text{EID}_{50} \). *

* EID\(_{50}\) = 50% Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. **PHARMACEUTICAL FORM**

A lyophilised vaccine pellet for reconstitution.

4. **PACKAGE SIZE**

10 ml vial of 5000 doses, containing at least \( 3.6 \log_{10} \text{EID}_{50} \) per dose.

5. **TARGET SPECIES**

Chickens.

6. **INDICATION(S)**

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For intranasal/ocular, spray or drinking water administration.

8. **WITHDRAWAL PERIOD**

Zero days.

9. **SPECIAL WARNING(S), IF NECESSARY**

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings.
10. **EXPIRY DATE**

{month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

Keep out of reach of children.

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

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PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 ≥ 3.6 log\(_{10}\) EID\(_{50}\). *

* EID\(_{50}\) = 50% Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE

10 ml vial of 10000 doses, containing at least 3.6 log\(_{10}\) EID\(_{50}\) per dose.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information.

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings.
10. **EXPIRY DATE**

{month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

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

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 ≥ 3.6 \( \log_{10} \text{EID}_{50} \) *  

* \( \text{EID}_{50} = 50\% \) Embryo infective dose: the titre required to infect 50\% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE

Multipack of 10 vials of 1000 doses, containing at least \( 3.6 \log_{10} \text{EID}_{50} \) per dose.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay. Wash and disinfect hands and equipment after vaccinating. See package insert for additional warnings.
10. **EXPIRY DATE**

{month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

Keep out of reach of children.

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2. STATEMENT OF ACTIVE SUBSTANCE(S)

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* $\text{EID}_{50} = 50\%$ Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE

Multipack of 10 vials of 2500 doses, containing at least $3.6 \log_{10} \text{EID}_{50}$ per dose.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings
10. **EXPIRY DATE**

{month/year}

11. **SPECIAL STORAGE PRECAUTIONS**

Store at 2-8°C. Protect from light. Do not freeze.

12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

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

13. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

14. **THE WORDS "KEEP OUT OF REACH OF CHILDREN"**

Keep out of reach of children.

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

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17. **MANUFACTURER'S BATCH NUMBER**

18. **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

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PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

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Nobilis IB 4-91.

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 ≥ 3.6 log₁₀ EID₅₀. *

* EID₅₀ = 50% Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. **PHARMACEUTICAL FORM**

A lyophilised vaccine pellet for reconstitution.

4. **PACKAGE SIZE**

Multipack of 10 vials of 5000 doses, containing at least 3.6 log₁₀ EID₅₀ per dose.

5. **TARGET SPECIES**

Chickens.

6. **INDICATION(S)**

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For intranasal/ocular, spray or drinking water administration.

8. **WITHDRAWAL PERIOD**

Zero days.

9. **SPECIAL WARNING(S), IF NECESSARY**

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings
10. EXPIRY DATE

{month/year}

11. SPECIAL STORAGE PRECAUTIONS

Store at 2-8°C. Protect from light. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

14. THE WORDS "KEEP OUT OF REACH OF CHILDREN"

Keep out of reach of children.

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

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

16. NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

17. MANUFACTURER'S BATCH NUMBER

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription
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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Live attenuated vaccine for chickens against Infectious Bronchitis Virus variant strain 4-91 ≥ 3.6 log₁₀ EID₅₀. *

* EID₅₀ = 50% Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

3. PHARMACEUTICAL FORM

A lyophilised vaccine pellet for reconstitution.

4. PACKAGE SIZE

Multipack of 10 vials of 10000 doses, containing at least 3.6 log₁₀ EID₅₀ per dose.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

Active immunisation of chickens to reduce the respiratory signs of avian Infectious Bronchitis caused by the variant strain IB 4-91.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

The sale, supply and/or use this product is/or may be prohibited in some Member State or parts of Member States. See Package leaflet for further information

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.

The product should not be used in future layers and breeders or chickens in lay.

Wash and disinfect hands and equipment after vaccinating.

See package insert for additional warnings
10. EXPIRY DATE

(month/year)

11. SPECIAL STORAGE PRECAUTIONS

Store at 2-8°C. Protect from light. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

14. THE WORDS "KEEP OUT OF REACH OF CHILDREN"

Keep out of reach of children.

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

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

16. NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

17. MANUFACTURER'S BATCH NUMBER

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription
PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Nobilis IB 4-91.

2. QUANTITY OF ACTIVE SUBSTANCE(S)
1000 doses, containing at least $3.6 \log_{10} \text{EID}_{50}$ Infectious Bronchitis Virus variant strain 4-91 per dose

3. ROUTES OF ADMINISTRATION
For intranasal/ocular, spray or drinking water administration.

4. BATCH NUMBER.

5. EXPIRY DATE

6. THE WORDS “FOR ANIMAL USE ONLY”
PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. QUANTITY OF ACTIVE SUBSTANCE(S)

2500 doses, containing at least 3.6 log10 EID50 Infectious Bronchitis Virus variant strain 4-91 per dose

3. ROUTES OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

4. BATCH NUMBER.

5. EXPIRY DATE

6. THE WORDS “FOR ANIMAL USE ONLY”
PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. QUANTITY OF ACTIVE SUBSTANCE(S)

5000 doses, containing at least $3.6 \log_{10} \text{EID}_{50}$ Infectious Bronchitis Virus variant strain 4-91 per dose

3. ROUTES OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

4. BATCH NUMBER.

5. EXPIRY DATE

6. THE WORDS “FOR ANIMAL USE ONLY”
PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB 4-91.

2. QUANTITY OF ACTIVE SUBSTANCE(S)

10000 doses, containing at least $3.6 \log_{10} EID_{50}$ Infectious Bronchitis Virus variant strain 4-91 per dose.

3. ROUTES OF ADMINISTRATION

For intranasal/ocular, spray or drinking water administration.

4. BATCH NUMBER.

5. EXPIRY DATE

6. THE WORDS “FOR ANIMAL USE ONLY”
B. PACKAGE INSERT
1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis IB 4-91.

2.1 **STATEMENT OF ACTIVE SUBSTANCE(S)**

Live attenuated Infectious Bronchitis Virus variant strain 4-91 $\geq 3.6 \log_{10} \text{EID}_{50}$. *

* $\text{EID}_{50} = 50\%$ Embryo infective dose: the titre required to infect 50% of the embryos inoculated with the virus.

2.2 **EXCIPIENT KNOWLEDGE OF WHICH IS ESSENTIAL FOR THE PROPER ADMINISTRATION OF THE VETERINARY MEDICINAL PRODUCT**

None.

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

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

4. **TARGET SPECIES**

Chickens.

5. **INDICATION(S)**

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

6. **DOSAGE FOR EACH SPECIES**

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

7. **METHOD AND ROUTE(S) OF 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. 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. 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 give the best responses and these should be the methods of choice, especially when vaccinating young chickens.

### 8. ADVICE ON CORRECT ADMINISTRATION

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

**Guideline:**
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. For prolonged immunity, chickens should be revaccinated every 6 weeks after the initial administration.

**Other information**
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.

The vaccine should be used within 2 hours after reconstitution and should not be stored.

Do not mix or administer with other products.

Only healthy chickens should be vaccinated.

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.

Wash and disinfect hands and equipment after vaccinating.
9. CONTRA-INDICATIONS

Nobilis IB 4-91 given at day-old can adversely affect the efficacy of Turkey Rhinotracheitis (TRT) vaccine given within 7 days, therefore this vaccination scheme is contra-indicated.

The product should not be used in future layers and breeders or chickens in lay.

10. UNDESIRABLE EFFECTS

Vaccination with Nobilis IB 4-91 may induce mild respiratory signs which may persist for a few days depending on the health and condition of the chickens.

11. WITHDRAWAL PERIOD

Zero days.

12. SPECIAL STORAGE CONDITIONS, IF ANY

Store at 2-8°C. Protect from light. Do not freeze.

13. SPECIAL WARNINGS, IF NECESSARY

The import, sale, supply and/or use of Nobilis IB 4-91 is/or may be prohibited in certain Member States on the whole or part of its territory pursuant to National animal health policy. Any person intending to import, sell, supply and/or use Nobilis IB 4-91 has to consult the relevant Member States competent Authorities on the current vaccination policies prior to the import, sale, supply and/or use.

The vaccine virus may spread from vaccinates to non-vaccinated chickens and appropriate care should be taken to separate vaccinates from non-vaccinates. Care should be taken to avoid spread of a vaccine virus from vaccinates to pheasants.

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

15. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED
16. **OTHER INFORMATION**

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

<table>
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<tr>
<th>Country</th>
<th>Company Name</th>
<th>Address</th>
<th>Phone</th>
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<td>Belgique/België</td>
<td>Intervet België N.V.</td>
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<td>Intervet AB</td>
<td>Västra Frölunda</td>
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<td>United Kingdom</td>
<td>Intervet U.K. Ltd.</td>
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