ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.25 ml:

Active substance
Inactivated whole cell suspension of *Ornithobacterium rhinotracheale* serotype A, strain B3263/91 1 x 10^7 cells *

* inducing a mean titre in the chickens of the potency test of at least 11.2 (log_2).

Adjuvant
Light liquid paraffin: 107.21 mg

Excipients
Traces of formaldehyde

For a list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *Ornithobacterium rhinotracheale* serotype A when this agent is involved.

Under field conditions passive immunity is transferred during lay for 43 weeks after the last vaccination of broiler breeders, resulting in a duration of passive immunity in broilers of at least 14 days after hatching.

4.3 Contraindications

Do not use in birds in lay.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

Allow vaccine to reach room temperature (15-25°C) before using the vaccine.
Shake well before use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies, a local transient swelling was found at post mortem examination in up to 40% of the birds for at least 14 days after subcutaneous vaccination. Under field conditions, sporadic local and systemic clinical reactions have been reported.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay (see section 4.3).

4.8 Interactions with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

The vaccination scheme consists of two injections with a dose of 0.25 ml, administered subcutaneously in the neck or intramuscularly in the breast. The first injection can be administered at an age of 6 - 12 weeks. The second injection has to be administered at least 6 weeks later at an age of 14 - 18 weeks.

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

No other undesirable effects have been observed after administration of a double dose when compared with a single dose of vaccine.
Occasionally hardened minor local swellings (0.5 – 2.0 cm) were observed which disappeared within 21 days after vaccination.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine
ATCvet code: QI 01AB07

The vaccine is to stimulate active immunity in broiler breeders in order to provide passive immunity to the progeny against *Ornithobacterium rhinotracheale* serotype A .

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin, Polysorbate 80, Sorbitan oleate, phosphate buffered aqueous solution

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf life

15 months
Shelf life after first opening: Use immediately after opening

6.4 Special precautions for storage

Store and transport at 2 - 8°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Carton box with one Polyethylene Terephthalate (PET) vial of 250 ml (1000 doses) or 500 ml (2000 doses), closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

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 material derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International
Wim de Körverstraat 35
NL-5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/036/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/01/2003

10. DATE OF REVISION OF THE TEXT

10.01.2008

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of the product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the product must consult the relevant Member States Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY ORUSE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER 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 OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes 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 veterinary medicinal product is intended to confer immunity is largely absent from the territory.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable

D. STATEMENT OF THE MRLs

- For the active principle of biological origin intended to produce immunity, Council Regulation (EEC) No 2377/90 does not apply.
- The adjuvants and excipients listed are included in Annex II of Council Regulation (EEC) No 2377/90.

Pharmacologically active substance	Animal Species	Other provisions
Mineral hydrocarbons, low to high viscosity including microcristalline waxes, approximately C10-C60; aliphatic, branched aliphatic and alicyclic compounds.	All food producing species	Excludes aromatic and unsaturated compounds
Polysorbate 80	All food producing species	
Sodium chloride	All food producing species	

- Sorbitan oleate (E 494), Potassium dihydrogen phosphate (E 340), Disodium hydrogen phosphate (E 339) and Potassium chloride (E 508) are approved as additives in foodstuffs for human consumption and therefore covered by Annex II of Council Regulation (EEC) No. 2377/90 for substances with an E- number[1] (with the exception of preservatives listed in part C of Annex III to Council Directive 95/2/EC[2].).

[1] OJ No L272 of 25.10.1996, p. 2
[2] OJ No L 61 of 18.3.1995, p. 1

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.25 ml:
Inactivated whole cell suspension of *Ornithobacterium rhinotracheale* serotype A strain B3263/91 1 x 10^7 cells *

* inducing a mean titre in the chickens of the potency test of at least 11.2 (log_2).

Light liquid paraffin: 107.21 mg
Traces of formaldehyde

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 PET vial with 250 ml (1000 doses)
1 PET vial with 500 ml (2000 doses)

5. TARGET SPECIES

Chickens

6. INDICATION(S)

For passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *Ornithobacterium rhinotracheale* serotype A when this agent is involved. Under field conditions passive immunity is transferred during lay for 43 weeks after the last vaccination of broiler breeders, resulting in a duration of passive immunity in broilers of at least 14 days after hatching.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection in the neck or intramuscular injection in the breast of one dose of 0.25 ml.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Oil adjuvanted vaccine
Do not use for birds in lay.
Accidental injection is dangerous – see package insert before use.

10. EXPIRY DATE

EXP: (Month/Year) ……/…..
Shelf life after first opening: Use immediately after opening

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2 - 8°C. Do not freeze.

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

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/036/001 (250 ml)
EU/2/02/036/002 (500 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot: ……

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

2. ACTIVE SUBSTANCE(S)

Inactivated whole cell suspension of *O. rhinotracheale*
Light liquid paraffin

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

250 ml (1000 doses)
500 ml (2000 doses)

4. TARGET SPECIES

Chickens

5. ROUTES OF ADMINISTRATION

s.c. injection or i.m. injection of one dose of 0.25 ml.

6. WITHDRAWAL PERIOD

Withdrawal period: 0 days

7. SPECIAL WARNINGS

Do not use for birds in lay.
Accidental self-injection is dangerous – see package insert

8. EXPIRY DATE

(Month/Year) ……/…..
Once broached: Use immediately

9. SPECIAL STORAGE CONDITIONS

Store and transport at 2 - 8°C. Do not freeze.

10. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

11. NAME OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Intervet International

12. MANUFACTURER'S BATCH NUMBER

Batch: ……

13. EU Number

EU/2/02/036/001 (250 ml)
EU/2/02/036/002 (500 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobilis OR inac emulsion for injection for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA

Marketing authorisation holder and manufacturer:

Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

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

Per dose of 0.25 ml:

Inactivated whole cell suspension of *Ornithobacterium rhinotracheale* serotype A strain B3263/91 1 x 10^7 cells *

* inducing a mean titre in the chickens of the potency test of at least 11.2 (log_2).

Light liquid paraffin: 107.21 mg
Traces of formaldehyde

4. INDICATION(S)

For passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *Ornithobacterium rhinotracheale* serotype A when this agent is involved. Under field conditions passive immunity is transferred during lay for 43 weeks after the last vaccination of broiler breeders, resulting in a duration of passive immunity in broilers of at least 14 days after hatching.

5. CONTRAINDICATIONS

Do not use for birds in lay

6. ADVERSE REACTIONS

In laboratory studies, a local transient swelling was found at post mortem examination in up to 40% of the birds for at least 14 days after subcutaneous vaccination. Under field conditions, sporadic local and systemic clinical reactions have been reported.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

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

Single dose of 0.25 ml.

Subcutaneous injection in the neck or intramuscular injection in the breast of the chicken.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach room temperature (15-25°C) before using the vaccine. Shake well before use.
Use sterile vaccination equipment.

Vaccination scheme:
The vaccination scheme consists of two injections with a dose of 0.25 ml, administered subcutaneously in the neck or intramuscularly in the breast. The first injection can be administered at an age of 6 - 12 weeks. The second injection has to be administered at least 6 weeks later at an age of 14 - 18 weeks.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport at 2 - 8°C.
Do not freeze.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

No other undesirable effects have been observed after administration of a double dose when compared with a single dose of vaccine.
Occasionally hardened minor local swellings (0.5 – 2.0 cm) were observed which disappeared within 21 days after vaccination.

Do not mix with any other vaccine/immunological product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

10.01.2008

15. OTHER INFORMATION

For animal treatment only.

The product contains the inactivated whole cells of *Ornithobacterium rhinotracheale* serotype A, strain B3263/91 mixed with an oil adjuvant. The vaccine is to stimulate active immunity in broiler breeders in order to provide passive immunity to the progeny against *Ornithobacterium rhinotracheale* serotype A.