SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IBmulti+ND+EDS emulsion for injection for chickens (DE, FR, SE)
Nobilis IBmulti-ND-EDS (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Active substances:

Inactivated viral antigens of:	
Avian infectious bronchitis virus strain M41	inducing ≥ 5.5 $\log_2$ VN units*
Avian infectious bronchitis virus strain 249G	inducing ≥ 4.0 $\log_2$ VN units*
Egg drop syndrome virus strain BC14	inducing ≥ 6.5 $\log_2$ HI units*
Newcastle disease virus strain Clone 30	inducing ≥ 4.0 $\log_2$ HI units per 1/50th of a dose* or containing ≥ 50 PD_{50} units

* serological response in chickens
VN = virus neutralising
HI = haemagglutination inhibiting
PD_{50} = protective dose in 50% of the test animals

Adjuvant:

Light liquid paraffin	215 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan mono-oleate
Glycine
Water for injections

Homogeneous and white to nearly white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each target species

Active immunisation of breeder and layer chickens for:
- Reduction of infection and prevention of egg drop caused by the Massachusetts serotype of infectious bronchitis virus (IBV);
- Reduction of egg drop and egg shell defects caused by the D274/D207 serotype of infectious bronchitis virus;
- Reduction of infection caused by Newcastle disease virus (NDV);
- Protection against egg drop caused by egg drop syndrome ’76 (EDS) virus.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity: one laying period.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

To the user:
This veterinary medicinal 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 veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens (breeders and layers):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A slight transient swelling may be felt at the site of vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

This vaccine should be given to chickens around 14-20 weeks of age but not later than 4 weeks before the expected onset of lay.
If live vaccines were used to prime chickens against infectious bronchitis and Newcastle disease, this vaccine should be given at least 4 weeks after the administration of the live vaccines.
Each chicken should be given 0.5 ml of vaccine intramuscularly in the thigh or chest muscle, or subcutaneously into the lower part of the neck.

Before using the vaccine allow it to reach ambient temperature (15 °C – 25 °C).
Shake the bottle vigorously before use and periodically during use.
Make sure that vaccination equipment is clean and sterile before use.
Do not use vaccination equipment with rubber parts, as the excipient may damage certain types of rubber.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of a double dose the reactions are not different from those observed after a single dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

{< > to be adjusted nationally}

<Any person intending to manufacture, import, possess, distribute, 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.>

<Official control authority batch release is required for this product according to national requirements.>

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA13.

Nobilis IBmulti+ND+EDS is an inactivated vaccine that contains two strains of infectious bronchitis virus (the Massachusetts serotype [M41] and a variant strain [249G] belonging to the D207/D274 serotype), a strain of Newcastle disease virus and a strain of egg drop syndrome '76 virus.

The antigens are inactivated with formalin and suspended in the aqueous phase of a water-in-oil adjuvant emulsion.

The vaccine is intended to stimulate active immunity against the Massachusetts and D207/D274 serotypes of infectious bronchitis virus, against Newcastle disease, and egg drop syndrome '76 virus. An enhanced immune response is obtained when the product is used for booster immunisation after priming the chickens with live vaccines, if available, against infectious bronchitis virus and Newcastle disease virus. Priming with egg drop syndrome vaccine is not necessary. The best results will be obtained if vaccination with the inactivated vaccine takes place at least 4 weeks after administration of the live primer. The vaccine contains an oil adjuvant.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Bottle of glass, hydrolytical class type II (Ph. Eur.) or of polyethylene terephthalate (PET). The bottles are closed with a nitryl rubber stopper and sealed with a colour coded aluminium cap.

Pack sizes:
Cardboard box with one glass or PET bottle of 250 ml (500 doses) or 500 ml (1000 doses).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater <or household waste>.
{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Number} {to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. {to be completed nationally}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY} {to be completed nationally}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IBmulti+ND+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.5 ml contains inactivated viral antigens of:

Avian infectious bronchitis virus strain M41	inducing ≥ 5.5 $\log_2$ VN units*
Avian infectious bronchitis virus strain 249G	inducing ≥ 4.0 $\log_2$ VN units*
Egg drop syndrome virus strain BC14	inducing ≥ 6.5 $\log_2$ HI units*
Newcastle disease virus strain Clone 30	inducing ≥ 4.0 $\log_2$ HI units per 1/50th of a dose* or containing ≥ 50 PD_{50} units

* serological response in chickens

3. PACKAGE SIZE

500 doses
1000 doses

4. TARGET SPECIES

Chickens (breeders and layers)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL Bottle (PET and glass)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IBmulti+ND+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

500 doses
1000 doses

Each dose of 0.5 ml contains inactivated viral antigens of:

Avian infectious bronchitis virus strain M41	inducing ≥ 5.5 $\log_2$ VN units*
Avian infectious bronchitis virus strain 249G	inducing ≥ 4.0 $\log_2$ VN units*
Egg drop syndrome virus strain BC14	inducing ≥ 6.5 $\log_2$ HI units*
Newcastle disease virus strain Clone 30	inducing ≥ 4.0 $\log_2$ HI units per $1/50^{th}$ of a dose* or containing ≥ 50 PD_{50} units

* serological response in chickens

3. TARGET SPECIES

Chickens (breeders and layers)

4. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{to be completed nationally}

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis IBmulti+ND+EDS emulsion for injection for chickens

2. Composition

Each dose of 0.5 ml contains:

Active substances:

Inactivated viral antigens of:	
Avian infectious bronchitis virus strain M41	inducing ≥ 5.5 $\log_2$ VN units*
Avian infectious bronchitis virus strain 249G	inducing ≥ 4.0 $\log_2$ VN units*
Egg drop syndrome virus strain BC14	inducing ≥ 6.5 $\log_2$ HI units*
Newcastle disease virus strain Clone 30	inducing ≥ 4.0 $\log_2$ HI units per $1/50^{th}$ of a dose* or containing ≥ 50 PD_{50} units

* serological response in chickens

VN = virus neutralising
HI = haemagglutination inhibiting
PD_{50} = protective dose in 50% of the test animals

Adjuvant:

Light liquid paraffin	215 mg

Homogeneous and white to nearly white emulsion.

3. Target species

Chickens (breeders and layers).

4. Indications for use

Active immunisation of breeder and layer chickens for:
- Reduction of infection and prevention of egg drop caused by the Massachusetts serotype of infectious bronchitis virus (IBV);
- Reduction of egg drop and egg shell defects caused by the D274/D207 serotype of infectious bronchitis virus;
- Reduction of infection caused by Newcastle disease virus (NDV);
- Protection against egg drop caused by egg drop syndrome ’76 (EDS) virus.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity: one laying period.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal 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 veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal 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.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
No information is available on the compatibility 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:
After administration of a double dose the reactions are not different from those observed after a single dose.

Special restrictions for use and special conditions for use:
{< > to be adjusted nationally}

<Any person intending to manufacture, import, possess, distribute, 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.>

<Official control authority batch release is required for this product according to national requirements.>

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens (breeders and layers):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A slight transient swelling may be felt at the site of vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Each chicken should be given 0.5 ml of vaccine.

The vaccine should be given intramuscularly in the thigh or chest muscle, or subcutaneously into the lower part of the neck.

The vaccine should be given to chickens around 14-20 weeks of age but not later than 4 weeks before the expected onset of lay.
If live vaccines were used to prime chickens against infectious bronchitis and Newcastle disease, the vaccine should be given at least 4 weeks after the administration of the live vaccines.

9. Advice on correct administration

Allow vaccine to reach ambient temperature (15 °C – 25 °C) before use.
Shake the bottle vigorously before use and periodically during use.
Make sure that vaccination equipment is clean and sterile before use.
Do not use vaccination equipment with rubber parts, as the excipient may damage certain types of rubber.

10. Withdrawal periods

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 which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}
Pack sizes:
Cardboard box with one glass or PET bottle containing 250 ml (500 doses) or 500 ml (1000 doses).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

Nobilis IBmulti+ND+EDS is an inactivated vaccine that contains two strains of infectious bronchitis virus (the Massachusetts serotype [M41] and a variant strain [249G] belonging to the D207/D274 serotype), a strain of Newcastle disease virus and a strain of egg drop syndrome ’76 virus. The antigens are inactivated with formalin and suspended in the aqueous phase of a water-in-oil adjuvant emulsion.
The vaccine is intended to stimulate active immunity against the Massachusetts and D207/D274 serotypes of infectious bronchitis virus, against Newcastle disease, and egg drop syndrome '76 virus. An enhanced immune response is obtained when the product is used for booster immunisation after priming the chickens with live vaccines, if available, against infectious bronchitis virus and Newcastle disease virus. Priming with egg drop syndrome vaccine is not necessary. The best results will be

obtained if vaccination with the inactivated vaccine takes place at least 4 weeks after administration of the live primer. The vaccine contains an oil adjuvant.

{to be completed nationally}

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle boxed area.