SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+ND+EDS emulsion for injection for chickens
FR: Nobilis RT Ponte emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml:

Active substances:
Inactivated viral antigens of:

IBV strain M41	inducing	≥ 5.5 $\log_2$ VN units*
IBV strain 249g	inducing	≥ 4.0 $\log_2$ VN units*
ART strain But1#8544	inducing	≥ 9.5 $\log_2$ ELISA units*
EDS'76 strain BC14	inducing	≥ 6.5 $\log_2$ HI units*
NDV 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

Adjuvant:
Liquid paraffin: 215 mg.

Excipients:

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

White to nearly white oily 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 eggshell defects caused by the D274/D207 serotype of infectious bronchitis virus;
- Reduction of infection caused by Newcastle disease virus;
- Prevention of respiratory signs and reduction of egg drop and eggshell defects related to avian rhinotracheitis (ART) virus (avian pneumovirus);
- Reduction of egg drop and eggshell defects related to egg drop syndrome (EDS) '76 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:

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

[1] A transient diffuse swelling which persists for about 14 days.

[<> to be adjusted nationally]
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 section "Contact details" of the package leaflet.

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

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, Rhinotracheitis and Newcastle disease, the 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.
Before using the vaccine allow it to reach ambient temperature (15 °C – 25 °C).
Shake the bottle vigorously before use and periodically during use.
Ensure 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 included in accordance with national requirements]:
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.

[To be included in accordance with national requirements]:
Official control authority batch release is required for this product.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA18.

The antigens are inactivated with formalin or β-propiolactone and suspended in the aqueous phase of a water-in-oil adjuvant emulsion, in order to enhance a prolonged stimulation of immunity.
The vaccine is intended to stimulate active immunity against avian rhinotracheitis virus, against the Massachusetts and D274/D207 serotypes of infectious bronchitis virus and 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 birds with live vaccines, if available, against infectious bronchitis, rhinotracheitis and Newcastle disease virus. Priming with egg drop syndrome live 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.

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).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Bottle of polyethylene terephthalate (PET), closed with a nitryl rubber stopper and sealed with a colour coded aluminium cap, containing 250 ml (500 doses) or 500 ml (1000 doses) of vaccine.

Pack sizes:
Cardboard box with one 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

[<> to be adjusted nationally]:
Medicines should not be disposed of via wastewater <or household waste>.

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

{Name} *[To be completed nationally]*

7. MARKETING AUTHORISATION NUMBER(S)

{MA number} *[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}

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).

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LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+ND+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.5 ml:

Inactivated viral antigens of:

IBV strain M41:	inducing	≥ 5.5 $\log_2$ VN units
IBV strain 249g:	inducing	≥ 4.0 $\log_2$ VN units
ART strain But1#8544:	inducing	≥ 9.5 $\log_2$ ELISA units
EDS'76 strain BC14:	inducing	≥ 6.5 $\log_2$ HI units
NDV strain Clone 30:	inducing	≥ 4.0 $\log_2$ HI units per $1/50^{th}$ of a dose
	or containing	≥ 50 PD_{50} units

3. PACKAGE SIZE

500 doses
1000 doses

4. TARGET SPECIES

Chickens (breeders and layers)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular 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

{Name} *[To be completed nationally]*

14. MARKETING AUTHORISATION NUMBERS

{MA number} *[To be completed nationally]*

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL PET BOTTLE (250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+ND+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

500 doses
1000 doses

Per dose of 0.5 ml:

Inactivated viral antigens of:

IBV strain M41:	inducing	≥ 5.5 $\log_2$ VN units
IBV strain 249g:	inducing	≥ 4.0 $\log_2$ VN units
ART strain But1#8544:	inducing	≥ 9.5 $\log_2$ ELISA units
EDS'76 strain BC14:	inducing	≥ 6.5 $\log_2$ HI units
NDV strain Clone 30:	inducing	≥ 4.0 $\log_2$ HI units per 1/50th of a dose
	or containing	≥ 50 PD_{50} units

3. TARGET SPECIES

Chickens (breeders and layers)

4. ROUTES OF ADMINISTRATION

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

{Name} *[To be completed nationally]*

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis RT+IBmulti+ND+EDS emulsion for injection for chickens

2. Composition

Per dose of 0.5 ml:

Active substances:
Inactivated viral antigens of:

IBV strain M41:	inducing	≥ 5.5 $\log_2$ VN units*
IBV strain 249g:	inducing	≥ 4.0 $\log_2$ VN units*
ART strain But1#8544:	inducing	≥ 9.5 $\log_2$ ELISA units*
EDS'76 strain BC14:	inducing	≥ 6.5 $\log_2$ HI units*
NDV 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

Adjuvant:
Liquid paraffin: 215 mg

White to nearly white oily 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 eggshell defects caused by the D274/D207 serotype of infectious bronchitis virus (IBV);
- Reduction of infection caused by Newcastle disease virus (NDV);
- Prevention of respiratory signs and reduction of egg drop and eggshell defects related to avian rhinotracheitis (ART) virus;
- Reduction of egg drop and eggshell defects related to egg drop syndrome (EDS) '76 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 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 included in accordance with national requirements]:
<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.>

[To be included in accordance with national requirements]:
<Official control authority batch release is required for this product.>

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

7. Adverse events

Chickens:

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

[1] A transient diffuse swelling which persists for about 14 days.

[<> to be adjusted nationally]:
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}.

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

Administer one dose of 0.5 ml vaccine per chicken via intramuscular injection in the thigh or chest muscle.
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, Rhinotracheitis 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 the vaccine to reach ambient temperature (15 °C – 25 °C) before use.
Shake the bottle vigorously before use and periodically during use.
Ensure 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).
Do not freeze.
Protect from light.

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

[<> to be adjusted nationally]:
Medicines should not be disposed of via wastewater <or household waste>.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{MA number} *[To be completed nationally]*

Pack sizes:
Cardboard box with one bottle of 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}

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 completed and adjusted as applicable nationally]

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

<Local representatives <and contact details to report suspected adverse reactions:>
[To be completed and adjusted as applicable nationally]

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
[To be completed and adjusted as applicable nationally]

17. Other information

Nobilis RT+IBmulti+ND+EDS is an inactivated viral vaccine against infectious bronchitis (Massachusetts and D274/D207), Newcastle disease, avian rhinotracheitis and egg drop syndrome '76 virus. The vaccine contains an oil adjuvant.

An enhanced immune response is obtained when the product is used for booster immunisation after priming the birds with live vaccines, if available, against infectious bronchitis, rhinotracheitis and Newcastle disease virus. Priming with egg drop syndrome live 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.

[To be completed nationally where applicable]:

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