ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.3 ml contains:

Active substances:

Avian metapneumovirus, strain BUT1 #8544, inactivated	≥ 19.0 U[1]
Infectious bronchitis virus, type Massachusetts, strain M41, inactivated	≥ 4.8 $\log_2$ HI[2]
Infectious bronchitis virus, type 793/B, strain 4/91, inactivated	≥ 5.7 $\log_2$ HI[2]
Newcastle disease virus, strain Ulster, inactivated	≥ 5.9 U[1]
Infectious bursal disease virus, strain GB02, inactivated	≥ 100.9 U[1]
Infectious bursal disease virus, strain 89/03, inactivated	≥ 88.6 U[1]
Avian reovirus, strain ARV-1, inactivated	≥ 11.5 U[1]
Avian reovirus, strain ARV-4, inactivated	≥ 11.4 U[1]
Eggdrop syndrome-1976 virus, strain BC14, inactivated	≥ 368.3 U[1]

[1] As determined in an *in vitro* antigenic mass ELISA potency test
[2] HI = hemagglutination inhibition. As determined in an *in vivo* potency test in chickens

Adjuvant:

Light liquid paraffin	128.6 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan oleate
PBS solution

Homogeneous, (nearly) white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

Indication for use:
For the active immunisation of chickens for:

- reduction of egg drop caused by avian metapneumovirus (AMPV).
- reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype).
- reduction of mortality and clinical signs caused by Newcastle disease virus (NDV).
- passive immunisation of the progeny of the vaccinated chickens to
  - reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus (IBDV).
  - reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

- reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).

Onset of immunity:
- IBV, NDV, IBDV, ARV and EDSV: 4 weeks post-vaccination.
- AMPV: 5 weeks post-vaccination
- IBDV and ARV in progeny: 1 day of age

Duration of immunity:
- AMPV, IBV, NDV, IBDV, ARV and EDSV: 80 weeks post-vaccination
- IBDV and ARV in progeny: 3 weeks of age

Cross protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).
Cross protection has been established for IBDV antigenic variant strains (variant E and GLS).
Cross protection has been established for ARV genotypes 2, 3 and 5.

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:

Uncommon (1 to 10 animals / 1000 animals treated):	Injection site lump[1]

[1] Generally disappearing within 3 weeks.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 3 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 is intended for use as a booster vaccination following priming with either live or inactivated vaccines in the vaccination schedule. Primary vaccinations should be performed with live or inactivated vaccines against infectious bronchitis virus (e.g. Nobilis IB 4-91, Nobilis IB Ma5), infectious bursal disease virus (e.g. Nobilis Gumboro D78, Innovax-ND-IBD) and avian reovirus (e.g. Nobilis Reo 1133, Nobilis Multriva REOm). The vaccine should be given at least 4 weeks after administration of the primary vaccination.

For intramuscular use.

Administer a single dose of 0.3 ml in the breast or thigh region from 8 weeks of age onwards, but no later than 3 weeks before the onset of lay.

Before use allow the vaccine to reach room temperature.
Shake well before use.
Syringes and needles must be sterile before use.
Follow standard aseptic procedures.

When primary vaccinations were performed against avian metapneumovirus (e.g. Nobilis Rhino CV) and/or Newcastle disease virus (e.g. Nobilis ND C2, Nobilis ND Clone 30, Innovax-ND-IBD), the vaccine should be given at least 4 weeks after administration of the primary vaccination.

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

No adverse reactions other than those mentioned in section 3.6 were observed after the administration of a double dose of vaccine.

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

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 may be required for this product according to national requirements.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA24.

The vaccine is intended to stimulate active immunity against avian rhinotracheitis virus, infectious bronchitis virus, Newcastle disease virus and eggdrop syndrome-1976 virus; and to stimulate active immunity in order to provide passive immunity to the progeny against infectious bursal (Gumboro) disease and avian reovirus.

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: 10 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Bottle of polyethylene terephthalate (PET) closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 1 bottle of 300 ml (1000 doses) or 600 ml (2000 doses).
Not all pack sizes may be marketed.

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

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/309/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/05/2024.

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated strains of avian metapneumovirus, infectious bronchitis virus, Newcastle disease virus, infectious bursal disease virus, avian reovirus and eggdrop syndrome-1976 virus.

3. PACKAGE SIZE

300 ml (1000 doses)
600 ml (2000 doses)

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from direct sunlight.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/309/001 300 ml
EU/2/24/309/002 600 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label - 300 ml / 600 ml PET bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

300 ml (1000 doses)
600 ml (2000 doses)

Inactivated strains of avian metapneumovirus, infectious bronchitis virus, Newcastle disease virus, infectious bursal disease virus, avian reovirus and eggdrop syndrome-1976 virus.

3. TARGET SPECIES

Chickens

4. ROUTES OF ADMINISTRATION

For intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator
Do not freeze.
Protect from direct sunlight.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS emulsion for injection for chickens

2. Composition

Each dose of 0.3 ml contains:

Active substances:

Avian metapneumovirus, strain BUT1 #8544, inactivated	≥ 19.0 U[1]
Infectious bronchitis virus, type Massachusetts, strain M41, inactivated	≥ 4.8 $\log_2$ HI[2]
Infectious bronchitis virus, type 793/B, strain 4/91, inactivated	≥ 5.7 $\log_2$ HI[2]
Newcastle disease virus, strain Ulster, inactivated	≥ 5.9 U[1]
Infectious bursal disease virus, strain GB02, inactivated	≥ 100.9 U[1]
Infectious bursal disease virus, strain 89/03, inactivated	≥ 88.6 U[1]
Avian reovirus, strain ARV-1, inactivated	≥ 11.5 U[1]
Avian reovirus, strain ARV-4, inactivated	≥ 11.4 U[1]
Eggdrop syndrome-1976 virus, strain BC14, inactivated	≥ 368.3 U[1]

[1] As determined in an *in vitro* antigenic mass ELISA potency test
[2] HI = hemagglutination inhibition. As determined in an *in vivo* potency test in chickens

Adjuvant:

Light liquid paraffin	128.6 mg

Homogeneous, (nearly) white emulsion.

3. Target species

Chickens.

4. Indications for use

Indication for use:
For the active immunisation of chickens for:

- reduction of egg drop caused by avian metapneumovirus (AMPV).
- reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype)
- reduction of mortality and clinical signs caused by Newcastle disease virus (NDV).
- passive immunisation of the progeny of the vaccinated chickens to
  - reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus (IBDV).
  - reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.
- reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).

Onset of immunity:

- IBV, NDV, IBDV, ARV and EDSV: 4 weeks post-vaccination
- AMPV: 5 weeks post-vaccination
- IBDV and ARV in progeny: 1 day of age

Duration of immunity:

- AMPV, IBV, NDV, IBDV, ARV and EDSV: 80 weeks post-vaccination
- IBDV and ARV in progeny: 3 weeks of age

Cross protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).
Cross protection has been established for IBDV antigenic variant strains (variant E and GLS).
Cross protection has been established for ARV genotypes 2, 3 and 5.

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 3 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:
No adverse reactions other than those mentioned in the section ‘Adverse events’ were observed after the administration of a double dose of vaccine.

Special restrictions for use and special conditions for use:
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.

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

7. Adverse events

Chickens:

Uncommon (1 to10 animals / 1000 animals treated):	Injection site lump[1]

[1] Generally disappearing within 3 weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 event to 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

For intramuscular use.

Administer a single dose of 0.3 ml in the breast or thigh region from 8 weeks of age onwards, but no later than 3 weeks before the onset of lay.

9. Advice on correct administration

This vaccine is intended for use as a booster vaccination following priming with either live or inactivated vaccines in the vaccination schedule. Primary vaccinations should be performed with live or inactivated vaccines against infectious bronchitis virus (e.g. Nobilis IB 4-91, Nobilis IB Ma5), infectious bursal disease virus (e.g. Nobilis Gumboro D78, Innovax-ND-IBD) and avian reovirus (e.g. Nobilis Reo 1133, Nobilis Multriva REOm). The vaccine should be given at least 4 weeks after administration of the primary vaccination.

Before use allow the vaccine to reach room temperature.
Shake well before use.
Syringes and needles must be sterile before use.
Follow standard aseptic procedures.

When primary vaccinations were performed against avian metapneumovirus (e.g. Nobilis Rhino CV) and/or Newcastle disease virus (e.g. Nobilis ND C2, Nobilis ND Clone 30, Innovax-ND-IBD), the vaccine should be given at least 4 weeks after administration of the primary vaccination.

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 direct sunlight.

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: 10 hours.

12. Special precautions for disposal

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 or pharmacist 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

EU/2/24/309/001-002

Pack sizes:
Cardboard box with 1 bottle of 300 ml (1000 doses) or 600 ml (2000 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:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: +420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

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Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: +30 210 989 7452

Latvija
Tel: + 37052196111

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: +420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220