ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Multriva REOm emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.3 ml contains:

Active substances:

Avian reovirus, strain ARV-1, inactivated	≥ 11.5 U[1]
Avian reovirus, strain ARV-4, inactivated	≥ 11.4 U[1]

[1] As determined in an *in vitro* antigenic mass ELISA potency test

Adjuvants:

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

For the active immunisation of chickens for passive immunisation of the progeny of the vaccinated chickens to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

Onset of immunity:

- 4 weeks after booster vaccination
- In progeny: 1 day of age

Duration of immunity:

- 80 weeks after booster vaccination
- In progeny: 3 weeks of age

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

For intramuscular use.

The vaccine is intended for use as a booster vaccination following priming with vaccines against avian reovirus. Primary vaccination should be performed with live vaccine (e.g. Nobilis Reo 1133) or with this vaccine.

- Use as primary vaccination:

Administer a single dose of 0.3 ml in the breast or thigh region from 7 weeks of age onwards.

- Use as booster vaccination:

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. 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.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA04.

The vaccine is intended to stimulate active immunity in order to provide passive immunity to the progeny against 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 products 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/2/24/333/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/02/2025

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

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 REOm emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated strains of avian reovirus.

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/2/24/333/001 300 ml
EU/2/24/333/002 600 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 REOm emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

Inactivated strains of avian reovirus.

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 REOm emulsion for injection for chickens

2. Composition

Each dose of 0.3 ml contains:

Active substances:

Avian reovirus, strain ARV-1, inactivated	≥ 11.5 U[1]
Avian reovirus, strain ARV-4, inactivated	≥ 11.4 U[1]

[1] As determined in an *in vitro* antigenic mass ELISA potency test

Adjuvants:

Light liquid paraffin	128.6 mg

Homogeneous, (nearly) white emulsion.

3. Target species

Chickens.

4. Indications for use

For the active immunisation of chickens for passive immunisation of the progeny of the vaccinated chickens to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

Onset of immunity:
- 4 weeks after booster vaccination
- In progeny: 1 day of age

Duration of immunity:
- 80 weeks after booster vaccination
- In progeny: 3 weeks of age

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.

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 events 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.

The vaccine is intended for use as a booster vaccination following priming with vaccines against avian reovirus. Primary vaccination should be performed with live vaccine (e.g. Nobilis Reo 1133) or with this vaccine.

- Use as primary vaccination:

Administer a single dose of 0.3 ml in the breast or thigh region from 7 weeks of age onwards.

- Use as booster vaccination:

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. The vaccine should be given at least 4 weeks after administration of the primary vaccination.

9. Advice on correct administration

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.

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/2/24/333/001-002

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

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

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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Tel: + 39 02 516861

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Tel: + 37052196111

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

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Tel.: + 36 1 439 4597

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Tel: + 39 02 516861

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

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Tel: + 351 214 465 700

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Tel: + 40 21 311 83 11

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Tel: + 385 1 6611339

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Tel: +420 233 010 242

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Puh/Tel: + 358 10 2310 750

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