

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Multiriva RT+IBm+ND+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	$\geq 19.0 U^1$
Infectious bronchitis virus, type Massachusetts, strain M41, inactivated	$\geq 4.8 \log_2 HI^2$
Infectious bronchitis virus, type 793/B, strain 4/91, inactivated	$\geq 5.7 \log_2 HI^2$
Newcastle disease virus, strain Ulster, inactivated	$\geq 5.9 U^1$
Eggdrop syndrome-1976 virus, strain BC14, inactivated	$\geq 368.3 U^1$

<sup>1</sup> As determined in an *in vitro* antigenic mass ELISA potency test

<sup>2</sup> HI = hemagglutination inhibition. As determined in an *in vivo* potency test in chickens

### Adjuvant:

Light liquid paraffin	128.6 mg
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### 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:

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

Onset of immunity:

- IBV, NDV and EDSV: 4 weeks post-vaccination
- AMPV: 5 weeks post-vaccination

Duration of immunity:

- AMPV, IBV, NDV and EDSV: 80 weeks post-vaccination

Cross-protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).

### 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 / 1 000 animals treated):	Injection site lump <sup>1</sup>
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<sup>1</sup>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). 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: QI01AA18.**

The vaccine is intended to stimulate active immunity against avian rhinotracheitis virus, infectious bronchitis virus, Newcastle disease virus and eggdrop syndrome-1976 virus.

## **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 (1 000 doses) or 600 ml (2 000 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/2/24/316/001-002

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 17/07/2024.

## **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 \(https://medicines.health.europa.eu/veterinary\)](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 Multiriva RT+IBm+ND+EDS emulsion for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

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

**3. PACKAGE SIZE**

300 ml (1 000 doses)  
600 ml (2 000 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/2/24/316/001 300 ml  
EU/2/24/316/002 600 ml

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

300 ml / 600 ml PET bottle

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis Multiriva RT+IBm+ND+EDS emulsion for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

300 ml (1 000 doses)  
600 ml (2 000 doses)

Inactivated strains of avian metapneumovirus, infectious bronchitis virus, Newcastle disease virus 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 Multiriva RT+IBm+ND+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 <sup>1</sup>
Infectious bronchitis virus, type Massachusetts, strain M41, inactivated	≥ 4.8 log <sub>2</sub> HI <sup>2</sup>
Infectious bronchitis virus, type 793/B, strain 4/91, inactivated	≥ 5.7 log <sub>2</sub> HI <sup>2</sup>
Newcastle disease virus, strain Ulster, inactivated	≥ 5.9 U <sup>1</sup>
Eggdrop syndrome-1976 virus, strain BC14, inactivated	≥ 368.3 U <sup>1</sup>

<sup>1</sup> As determined in an *in vitro* antigenic mass ELISA potency test

<sup>2</sup> 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

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

#### Onset of immunity:

- IBV, NDV and EDSV: 4 weeks post-vaccination
- AMPV: 5 weeks post-vaccination

#### Duration of immunity:

- AMPV, IBV, NDV and EDSV: 80 weeks post-vaccination

Cross-protection has been established for IBV strains QX-D388 (GI-19 genotype), Var2 (GI-23 genotype) and Q1 (GI-16 genotype).

### 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 to 10 animals / 1 000 animals treated):	Injection site lump <sup>1</sup>
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<sup>1</sup> 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.

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). 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/2/24/316/001-002

#### Pack sizes:

Cardboard box with 1 bottle of 300 ml (1 000 doses) or 600 ml (2 000 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) (<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

#### **Lietuva**

Tel: + 37052196111

#### **Република България**

Тел: + 359 28193749

#### **Luxembourg/Luxemburg**

Tél/Tel: + 32 (0)2 370 94 01

#### **Česká republika**

Tel: +420 233 010 242

#### **Magyarország**

Tel.: + 36 1 439 4597

#### **Danmark**

Tlf: + 45 44 82 42 00

#### **Malta**

Tel: + 39 02 516861

#### **Deutschland**

Tel: + 49 (0)8945614100

#### **Nederland**

Tel: + 32 (0)2 370 94 01

#### **Eesti**

Tel: + 37052196111

#### **Norge**

Tlf: + 47 55 54 37 35

#### **Ελλάδα**

Τηλ: + 30 210 989 7452

#### **Österreich**

Tel: + 43 (1) 256 87 87

#### **España**

Tel: + 34 923 19 03 45

#### **Polska**

Tel.: + 48 22 18 32 200

**France**

Tél: + 33 (0)241228383

**Hrvatska**

Tel: + 385 1 6611339

**Ireland**

Tel: + 353 (0) 1 2970220

**Ísland**

Sími: + 354 535 7000

**Italia**

Tel: + 39 02 516861

**Κύπρος**

Τηλ: +30 210 989 7452

**Latvija**

Tel: + 37052196111

**Portugal**

Tel: + 351 214 465 700

**România**

Tel: + 40 21 311 83 11

**Slovenija**

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**Slovenská republika**

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