

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Coryza suspension for injection for chicken

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.25 ml dose contains:

Active substances:

Avibacterium paragallinarum, serotype A, strain 083, inactivated ≥ 1 CPD₇₀*

Avibacterium paragallinarum, serotype B, strain Spross, inactivated ≥ 1 CPD₇₀

Avibacterium paragallinarum, serotype C, strain H18, inactivated ≥ 1 CPD₇₀

* CPD₇₀: 70% chicken protective dose

Adjuvant:

Purified saponin: 500 µg

Excipients:

Qualitative composition of excipients and other constituents
Phosphate buffer
Antifoam
Sodium chloride
Water for injections

Yellow-brown, opalescent suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chicken.

3.2 Indications for use for each target species

Active immunisation of chickens to reduce clinical signs of Infectious Coryza, caused by *Avibacterium paragallinarum* (*A. paragallinarum*) serotypes A, B, and C and bacteria reisolation rate.

Onset of immunity: 2 weeks post-vaccination.

Duration of immunity: at least 52 weeks post-vaccination.

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:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling ¹ .
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¹ A soft to hard transient swelling (10 mm) that disappears within two 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 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 4-6 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

Intramuscular use.

Before use, allow the vaccine to reach room temperature. Shake vigorously prior to and regularly during application. Use sterile syringe and needles.

Administer one dose of 0.25 ml of vaccine by intramuscular injection to chickens from 10-12 weeks old and a revaccination not later than 4-6 weeks before lay. Interval between vaccinations should be at least 4 weeks.

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

No other local and systemic reactions are observed after vaccination with a double dose, than those observed after vaccination with 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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AB04

The active ingredients are inactivated germs of serotypes A, B and C of *A. paragallinarum*, which stimulate homologous (serotype-specific) active immunity against Infectious Coryza, caused by *A. paragallinarum* serotypes A, B and C. The inactivated bacteria are incorporated in a purified saponin adjuvant in order to enhance a prolonged stimulation of immunity.

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: 1 year in glass vials and 2 years in PET vials.

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

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

Glass (type I) vial or PET vial containing 250 ml (1000 doses) or 500 ml (2000 doses) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:

Cardboard box with 1 glass or PET vial of 250 ml (1000 doses)

Cardboard box with 1 glass or PET vial of 500 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.
{< > to be adjusted nationally}

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{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.>
{< > to be adjusted nationally}

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 Coryza suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.25 ml dose contains:

A. paragallinarum

- serotype A, strain 083, inactivated ≥ 1 CPD₇₀*
- serotype B, strain Spross, inactivated ≥ 1 CPD₇₀
- serotype C, strain H18, inactivated ≥ 1 CPD₇₀

*CPD₇₀: 70% chicken protective dose

3. PACKAGE SIZE

250 ml (1000 doses)

500 ml (2000 doses)

4. TARGET SPECIES

Chicken

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

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS VIAL OR PET VIAL 250 ml & 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Coryza suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

250 ml (1000 doses)

500 ml (2000 doses)

Each 0.25 ml dose contains:

A. paragallinarum

- serotype A, strain 083, inactivated ≥ 1 CPD₇₀*

- serotype B, strain Spross, inactivated ≥ 1 CPD₇₀

- serotype C, strain H18, inactivated ≥ 1 CPD₇₀

*CPD₇₀: 70% chicken protective dose

3. TARGET SPECIES

Chicken

4. ROUTES OF ADMINISTRATION

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 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 Coryza suspension for injection for chicken

2. Composition

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* CPD₇₀: 70% chicken protective dose

Adjuvant:

Purified saponin: 500 µg

Yellow-brown, opalescent suspension.

3. Target species

Chicken.

4. Indications for use

Active immunisation of chickens to reduce clinical signs of Infectious Coryza, caused by *Avibacterium paragallinarum* (*A. paragallinarum*) serotypes A, B, and C and bacteria reisolation rate.

Onset of immunity: 2 weeks post-vaccination.

Duration of immunity: at least 52 weeks post-vaccination.

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:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Laying birds:

Do not use in birds in lay and within 4-6 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 other local and systemic reactions are observed after vaccination with a double dose, than those observed after vaccination with a single dose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chicken:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling ¹ .
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¹ A soft to hard transient swelling (10 mm) that disappears within two weeks.

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

Administer one dose of 0.25 ml of vaccine by intramuscular injection to chickens from 10-12 weeks old and a revaccination not later than 4-6 weeks before lay. Interval between vaccinations should be at least 4 weeks.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature.
Shake vigorously prior to and regularly during application.
Use sterile syringe and needles.

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

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.

{<> to be adjusted nationally}

13. Classification of veterinary medicinal products

<Veterinary medicinal product subject to prescription.>

{<> to be adjusted nationally}

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

Pack sizes:

Cardboard box with 1 glass or PET vial of 250 ml (1000 doses)

Cardboard box with 1 glass or PET vial of 500 ml (2000 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 representatives <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

The active ingredients are inactivated germs of serotypes A, B and C of *A. paragallinarum*, which stimulate homologous (serotype-specific) active immunity against Infectious Coryza, caused by *A. paragallinarum* serotypes A, B and C. The inactivated bacteria are incorporated in a purified saponin adjuvant in order to enhance a prolonged stimulation of immunity.

{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