

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the Veterinary Medicinal Product

Nobilis Coryza Inac Emulsion for Injection for chickens.

### 2. Qualitative and Quantitative Composition (per 0.5 ml dose)

Active Substances:

- Avibacterium paragallinarum, serotype A, strain 083, inactivated  $\geq 1$  CPD70
- Avibacterium paragallinarum, serotype B, strain Spross, inactivated  $\geq 1$  CPD70
- Avibacterium paragallinarum, serotype C, strain H18, inactivated  $\geq 1$  CPD70

(CPD70: 70% Chicken Protective Dose)

Adjuvant:

- Light liquid paraffin: 214.42 mg

Excipients:

- Polysorbate 80
- Sorbitan monooleate
- Sodium chloride
- Water for injections

Appearance: Homogeneous white to nearly white water-in-oil emulsion.

### 3. Clinical Particulars

#### 3.1 Target Species

Chicken.

#### 3.2 Indications for Use

Active immunization of chickens for partial protection against infectious coryza caused by Avibacterium paragallinarum serotypes A, B, and C.

Duration of Immunity:

- 6 weeks after single vaccination
- 1 year after booster vaccination

### 3.3 Contraindications

None.

### 3.4 Special Warnings

Only vaccinate healthy animals.

### 3.5 Special Precautions

For the animal: None.

For the person administering the product:

- Contains mineral oil. Accidental self-injection may cause severe pain and swelling, especially in joints or fingers, potentially leading to loss of the affected finger without prompt treatment.
- Seek immediate medical attention even for small injections and take the package leaflet to the doctor.
- Delayed symptoms (>12 hours) require a second medical evaluation.
- To the physician: Early surgical intervention may be required.

### 3.6 Adverse Reactions

Very common (>1 in 10 treated chickens):

- Local reaction at injection site (may occur after initial or booster dose).

### 3.7 Use During Pregnancy, Lactation, or Laying

Not applicable.

### 3.8 Interactions with Other Medicines

No data available. Decisions regarding combination use should be case-specific.

### 3.9 Route and Dosage

Route: Subcutaneous

- Single dose of 0.5 ml per chicken from 5 weeks of age.

Laying hens and breeders:

- Primary vaccination: 0.5 ml between 5-10 weeks of age

- Booster: 0.5 ml at 16-18 weeks, a few weeks before laying starts

### 3.10 Overdose

No additional adverse effects observed beyond those listed under section 3.6.

### 3.11 Restrictions on Use

None applicable.

### 3.12 Withdrawal Period

Zero days.

## 4. Immunological Properties

ATCvet Code: QI01AB04

Stimulates active immunity against *Avibacterium paragallinarum* serotypes A, B, and C in chickens.

## 5. Pharmaceutical Particulars

### 5.1 Major Incompatibilities

Do not mix with any other veterinary product.

### 5.2 Shelf Life

- 15 months in sales packaging.

### 5.3 Storage Precautions

- Store refrigerated (2-8 °C)
- Do not freeze
- Protect from light

### 5.4 Packaging

- Glass (Type II) or PET vials
- 250 ml (500 doses)
- 500 ml (1000 doses)

- Sealed with nitrile rubber stopper and aluminum cap

#### 5.5 Disposal

Do not dispose via wastewater or household waste. Follow local regulations for disposal.

#### 6. Marketing Authorisation Holder

Intervet Nederland B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands

#### 7. Marketing Authorisation Number

REG NL 7144

#### 8. First Authorisation Date

January 16, 1992

#### 9. Last SPC Revision Date

March 31, 2025

#### 10. Classification of Veterinary Medicinal Product

Prescription-only veterinary medicine.