## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rhino CV lyophilisate for oculonasal suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

**Active substances:**
Avian metapneumovirus, strain 11/94, Live: $10^{1.5}$ - $10^{3.7}$ $TCID_{50}$*.

*Tissue Culture Infective Dose 50%

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| **Lyophilisate:** |
| Pancreatic digest of casein |
| Sorbitol |
| Gelatine |
| Disodium phosphate dihydrate |
| Water for injections |
| **Solvent:** |
| Patent Blue V (E131) |
| Potassium dihydrogen phosphate |
| Disodium phosphate dihydrate |
| Disodium edetate dihydrate |
| Sodium chloride |
| Water for injections |

Lyophilisate: white/off-white cake
Solvent (Solvent Oculo/Nasal): blue-coloured solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chicken.

### 3.2 Indications for use for each target species

For broilers, future layers and breeders from one day of age.

*Broilers, future layers and breeders*
Active immunisation in order to reduce the frequency and the severity of clinical signs due to infection with avian rhinotracheitis virus (avian metapneumovirus).

Onset of immunity: 3 weeks.
Duration of immunity: 16 weeks post-vaccination.

*Future layers and breeders*
Priming with Nobilis Rhino CV, followed by a second vaccination with an inactivated vaccine containing the avian rhinotracheitis virus strain But1#8544 before the onset of lay results in a reduction of the clinical signs including egg drop, caused by infection with avian rhinotracheitis virus. Protective immunity is maintained for the normal laying period.

### 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:

In order to reduce the circulation of the vaccine strain, all susceptible animals on the site have to be vaccinated properly and preferably at the same time. The vaccine virus can spread to other susceptible species with which they have direct contact. It was shown that the spreading has negligible impact on turkeys, which together with chickens constitute the species that are most susceptible to avian rhinotracheitis virus.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chicken:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Nasal discharge[1], Cough[1] |

[1] Mild. Between 2 to 7 days after administration for 1 to 2 days.

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.

### 3.7 Use during pregnancy, lactation or lay

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

## 3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with vaccines against infectious bronchitis containing strain H120 and against Newcastle disease containing strains Clone 30 or C2 and infectious bronchitis vaccine (strain IB Ma5) when given on day 1 (the efficacy of the IB Ma5 vaccine has not been investigated).
The company's live vaccine against Gumboro disease (infectious bursal disease) containing the D78 strain can be given 7 days after Nobilis Rhino CV.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary product therefore needs to be made on a case-by-case basis.

## 3.9 Administration routes and dosage

Oculonasal use via eye- or nose-drop method or via coarse spray, one dose per bird from 1 day old.

Oculonasal route
Reconstitute the freeze-dried vaccine in clean, disinfectant- and antiseptic-free water to which 2% liquid skimmed milk is added or in Solvent Oculo/Nasal and administer by means of a standardised dropper. The amount of fluid required for eye- or nose-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1.000 doses or 84 ml per 2500 doses are used. Apply one drop in a nare or eye. Check that the drop is entirely absorbed before releasing the bird.

After reconstitution the suspension looks homogeneous opalescent to slightly white.
After reconstitution in Solvent Oculo/Nasal the suspension looks clear.

Spray vaccination
The vaccine must be reconstituted with clean, disinfectant- and antiseptic-free water to which 2% of liquid skimmed milk is added. The appropriate number of vials must be opened under water. The volume of vaccine suspension must be sufficient to ensure a homogeneous vaccination of the birds. Depending on the age of the chickens to be vaccinated and the rearing system, take 250 to 500 ml of water per 1.000 doses. The vaccine suspension is to be sprayed evenly over the appropriate number of animals at a distance of 30-40 cm with a regular spraying apparatus, preferably when the animals sit together under a dim light. The spray apparatus must be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only.
If applicable, reduce ventilation to prevent loss of spray.

After reconstitution the suspension looks clear.

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

Administration of tenfold the maximum dose by the recommended routes has not resulted in any other effect on the target species than those described under section 3.6.

## 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: QI01AD01

The vaccine contains the live attenuated strain 11/94 of avian metapneumovirus, sub-type B. Upon administration, the vaccine induces active immunity in chickens against avian metapneumovirus. The growth characteristic of the vaccine strain in chicken embryo fibroblasts allows differentiation from field virus. Indicative results can be obtained by specialised laboratories.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except Solvent Oculo/Nasal.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life of the diluent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 2 hours.

### 5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Solvent:
Store below 25 °C.
Do not freeze.

### 5.4 Nature and composition of immediate packaging

Glass (Type I) vials of 250, 500, 1.000, 2.500, 5.000, 10.000 or 25.000 doses closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.

Solvent: polyethylene vials closed with a halogenobutyl rubber stopper and sealed with a colour coded cap.

Pack sizes:
Cardboard box containing 1, 2, 5, 10, 20 or 50 vials.
Cardboard box with 1 or 10 vials of diluent (35 ml or 84 ml).

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.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

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 Ireland Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/190/001

## 8. DATE OF FIRST AUTHORISATION

17/06/2005

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

11/09/2026

## 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).