## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2 lyophilisate for oculonasal suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of reconstituted vaccine:

**Active substance:**
Live attenuated Newcastle disease virus (NDV) strain C2: 5.7 - 7.5 $\log_{10}$ $EID_{50}$* .

*$EID_{50}$ = 50% Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Sorbitol |
| Hydrolysed gelatine |
| Pancreatic digest of casein |
| Disodium phosphate dihydrate |
| Purified water |

Lyophilisate.:
Vials: white/off-white coloured pellet.
Cups: white/off-white, predominantly sphere shaped.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens.

### 3.2 Indications for use for each target species

Active immunisation of chickens against Newcastle disease virus to reduce clinical signs and mortality.

Onset of immunity: 2 weeks after vaccination of seronegative animals.
Duration of immunity: 5 weeks after vaccination of seronegative animals.

Onset of protection is demonstrated at 2 weeks after vaccination of animals with maternally derived antibodies.

Duration of immunity is in accordance with the vaccination programme.

### 3.3 Contraindications

Do not vaccinate clinically ill (especially respiratory disease) or stressed birds.

### 3.4 Special warnings

Vaccinate healthy animals only.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine virus may spread to unvaccinated birds up to 10 days post vaccination. This spread does not induce clinical signs but may lead to seroconversion in unvaccinated chickens.

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

The vaccine can be pathogenic for humans. Since this vaccine has been prepared with live, attenuated viruses, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.
In case of spray administration, personal protective equipment consisting of masks with eye protection should be worn when handling the veterinary medicinal product.
Wash and disinfect hands and equipment after vaccination.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens:

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Head shake - behavioural disorder[1],<br>Blinking[1]. |

[1] May be observed when ice-cold vaccine is administered via the eye/nose drop method.

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 to 1-day old chicks on the same day, but not mixed, with Innovax-ILT, or the Nobilis live vaccines against rhinotracheitis (strain 11/94). Marek's disease (strains CVI988-FC126) or infectious bronchitis (strain IB Ma5) are compatible with Nobilis ND C2 when non mixed and given on day 1. The efficacy of the Marek and IB Ma5 vaccines has not been investigated.
Safety and efficacy data are available which demonstrate that the Nobilis live vaccine against Infectious bursal disease vaccine (strain D78) can be given 7 days after Nobilis ND C2.
Safety and efficacy data are available which demonstrate that Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-IBD.
Safety and efficacy data are available which demonstrate that Nobilis ND C2 can be administered to day-old chicks that are vaccinated either by the subcutaneous or *in ovo* route with Innovax-ND-ILT.

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 medicinal product therefore needs to be made on a case by case basis.

### 3.9 Administration routes and dosage

For oculonasal use via intranasal/ocular or coarse spray administration.
Single vaccination with one dose per animal from 1 day of age onwards.

The vaccine may be delivered as a freeze-dried cake in a glass vial or as freeze-dried spheres in cups. In case of the product presented in cups, do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Each container should be used immediately and completely after opening. After reconstitution the suspension looks clear.

Intranasal/ocular administration
Reconstitute the vaccine with the appropriate amount of a suitable solvent and administer by means of a standardised dropper (of which the droplet size is known and consistent). Sterile distilled water or phosphate buffered saline can be used. The amount of solvent required for eye- or nose-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1000 doses is used. One drop should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Coarse spray administration
Reconstitute the vaccine in cool, clean water, to which 2% skimmed milk may be added. The vials should be opened under water or the content of the cup(s) should be poured into water. Chlorinated water should not be used. In both cases mix the water containing vaccine well before use.
The volume of solvent for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system, but 250 to 500 ml of water per 1000 doses is suggested. The vaccine suspension should be sprayed evenly over the birds at a distance of 30-40 cm, preferably when the birds are sitting together in dim light. If applicable, reduce or stop ventilation to prevent loss of spray.
The water and spray apparatus should be free from sediments, corrosion and traces of disinfectants or antiseptics and ideally should be used for vaccination purposes only.

Vaccination programme
The vaccine can be given from 1 day of age onwards. Because the immunity which is induced by the vaccination is not long lasting, an extended vaccination programme should be followed. To maintain a required level of immunity, chickens should receive a secondary vaccination 2-3 weeks after administration of this vaccine, with a live vaccine containing the more immunogenic Clone 30 strain.

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

No other signs than after a single dose are seen after administration of ten times the maximum dose via the recommended routes.

### 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: QI01AD06.

To stimulate active immunity against Newcastle disease in chickens.
The attenuated C2 strain is lentogenic and of low pathogenicity and is therefore suitable from 1 day of age.
Priming effect of ND C2 has been demonstrated exclusively by secondary vaccination of chickens with the live NDV vaccine containing the more immunogenic Clone 30 strain.

## 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 reconstitution according to directions: 3 hours.

### 5.3 Special precautions for storage

Store in a refrigerator (2° C –8° C).
Do not freeze.
Protect from light.

Store below 25 °C after reconstitution.

### 5.4 Nature and composition of immediate packaging

Glass vial (hydrolytic glass type I or glass type II), closed with a with halogenobutyl rubber stopper and metal cap.

Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

Pack sizes:
Cardboard box with 1 or 10 vial(s) of 500 doses, 1000 doses, 2500 doses, 5000 doses, 10 000 doses or 25 000 doses.
PET plastic boxes with 12 cups of 1000 doses, 2500 doses, 5000 doses or 10 000 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 Ireland Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/187/001

## 8. DATE OF FIRST AUTHORISATION

03 June 2005

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

17 November 2023

## 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).