

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

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

Nobilis ND C2 lyophilisate for oculonasal suspension for chickens

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live attenuated Newcastle disease virus (NDV) strain C2: 5.7 - 7.5 log<sub>10</sub> EID<sub>50</sub>/dose

**3. PHARMACEUTICAL FORM**

Lyophilisate for oculonasal suspension

**4. PACKAGE SIZE**

500 doses  
1000 doses  
2500 doses  
5000 doses  
10 000 doses  
25 000 doses

**5. TARGET SPECIES**

Chickens

**6. INDICATION(S)**

For active immunisation of chickens against Newcastle disease virus.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}  
Once reconstituted use within 3 hours.

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Do not freeze. Protect from light.  
Store below 25°C after reconstitution.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material in accordance with local requirements.

## **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

## **14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

## **16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4626

## **17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

## **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

### **GLASS VIAL**

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

Nobilis ND C2 lyophilisate for ocular suspension for chickens

#### **2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

5.7 - 7.5 log<sub>10</sub> EID<sub>50</sub> NDV strain C2

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

500 doses  
1000 doses  
2500 doses  
5000 doses  
10 000 doses  
25 000 doses

**4. ROUTE(S) OF ADMINISTRATION**

Oculonasal use (incl. spray).

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}  
Once reconstituted use within 3 hours

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PACKAGE LEAFLET:**  
**Nobilis ND C2 lyophilisate for oculonasal suspension for chickens**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER  
AND OF THE MANUFACTURING AUTHORISATION HOLDER  
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:  
MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer responsible for batch release:  
Intervet International B.V.  
Wim de Körverstraat 35  
NL- 5831 AN Boxmeer  
The Netherlands

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

Nobilis ND C2 lyophilisate for oculonasal suspension for chickens

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER  
INGREDIENT(S)**

Live attenuated Newcastle disease virus (NDV) strain C2: 5.7-7.5 log<sub>10</sub> EID<sub>50</sub>\* per dose.

\*EID<sub>50</sub> = 50% Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated

**4. INDICATION(S)**

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.

**5. CONTRAINDICATIONS**

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

## **6. ADVERSE REACTIONS**

Blinking or headshaking may be observed when ice-cold vaccine is administered via the eye/nose drop method.

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Chickens.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Administration via eye- or nose-drop method or via (coarse) spray.  
Single vaccination with one dose per animal from 1 day of age onwards.

### Eye- or nose-drop administration

Reconstitute the vaccine with the appropriate amount of a suitable diluent 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 diluent 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.

### Spray

Reconstitute the vaccine in cool, clean water, to which 2% skimmed milk may be added. Chlorinated water should not be used. The water and spray apparatus should be free from sediments, corrosion and traces of disinfectants or antiseptics. Ideally the apparatus should be used for vaccination purposes only. The volume of diluent 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.

### Vaccination programme

Nobilis ND C2 can be given from 1 day of age onwards. Because the immunity which is induced by vaccination with Nobilis ND C2 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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Once reconstituted use the vaccine within 3 hours.

## 10. WITHDRAWAL PERIOD(S)

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.  
Store below 25°C after reconstitution.  
Do not use after the expiry date stated on the label.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

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:

Live Newcastle disease vaccines may cause a mild transient conjunctivitis in the person administering the vaccine. Appropriate measures should be taken to prevent this.

Wash and disinfect hands and equipment after vaccinating. When used by spray, contact of eyes and airways with the vaccine virus should be prevented. Personal protective equipment consisting of a face mask should be worn when spraying the vaccine.

Lay:

Not to be used during lay or within 4 weeks before the start of the laying period (as the safety of this has not been investigated).

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that Innovax-ILT , or Innovax-ND-IBD, or the Nobilis live vaccine against avian pneumovirus (strain 11/94) , Marek's disease (strains CVI988 and FC126) and infectious bronchitis (strain IB Ma5) can be administered to 1-day old chicks on the same day, but not mixed, with Nobilis ND C2 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.

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.

Overdose (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

Do not use with any other veterinary medicinal product, except the products mentioned above.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

July 2020

**15. OTHER INFORMATION**

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.

Cardboard box containing 1 or 10 vials of glass (hydrolytic glass type I or glass type II) with halogenobutyl rubber stopper and metal cap. Contents per vial: 500, 1000, 2500, 5000, 10 000 or 25 000 doses.

Not all pack sizes may be marketed.

Approved 22 September 2020

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.