LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (VIALS) with 1 or 10 vials of lyophilisate
PET PLASTIC BOX (CUPS) with 12 cups of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2 lyophilisate for oculonasal suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

*EID_{50}: 50% Embryo infective dose

3. PACKAGE SIZE

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

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal use (incl. spray).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

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

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3020

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL – Lyophilisate vials 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

5.7 - 7.5 $\log_{10}$ EID_{50} NDV, C2/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate cups

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 doses
2500 doses
5000 doses
10 000 doses

Live NDV, C2

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis ND C2 lyophilisate for oculonasal suspension for chickens

2. 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

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

3. Target species

Chickens.

4. Indications for use

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. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Laying birds:
Not to be used during lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that Innovax-ILT, or the Nobilis live vaccine against rhinotracheitis (strain 11/94). can be administered to 1-day old chicks on the same day, but not mixed with Nobilis ND C2.
Marek's disease (strain CVI988-FC126) or infectious bronchitis vaccine (strain IB Ma5) are compatible with Nobilis ND C2 when not 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.

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

Special restrictions for use and special conditions for use:

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Head shake - behavioural disorder[1], 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 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 using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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

9. Advice on correct administration

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.

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.
Store below 25 °C after reconstitution.

Do not use this veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 3 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3020

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.

15. Date on which the package leaflet was last revised

November 2023

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:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. 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.

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

Approved 26 April 2024