

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (VIALS)
PET PLASTIC BOX (CUPS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2 lyophilisate for ocular suspension for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live attenuated Newcastle disease virus (NDV) strain C2: 5.7 - 7.5 log₁₀ EID₅₀/dose

3. PHARMACEUTICAL FORM

Lyophilisate for ocular suspension

4. 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

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 log₁₀ EID₅₀ 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

Ocular 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.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND C2 lyophilisate for ocular and nasal suspension



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live ND virus, strain C2

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

1000 doses (3-100 spheres)
2500 doses (3-100 spheres)
5000 doses (3-100 spheres)
10 000 doses (3-100 spheres)

4. ROUTE(S) OF ADMINISTRATION

See package leaflet.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:
Nobilis ND C2 lyophilisate for ocularonasal 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 ocularonasal 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 log₁₀ EID₅₀* per dose.

*EID₅₀ = 50% Embryo infective dose: the virus titre required to produce infection in 50% of the embryos inoculated

Vials: white/off-white coloured pellet.

Cups: white/off-white, predominantly sphere shaped.

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 oculonasal use or via (coarse) spray.
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.

Oculonasal 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. 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. After reconstitution the suspension looks clear. 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 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 (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

December 2022

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.

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

Pack sizes:

Cardboard box with 1 or 10 vials of 500 doses.

Cardboard box with 1 or 10 vials of 1000 doses.

Cardboard box with 1 or 10 vials of 2500 doses.

Cardboard box with 1 or 10 vials of 5000 doses.

Cardboard box with 1 or 10 vials of 10000 doses.

Cardboard box with 1 or 10 vials of 25000 doses.

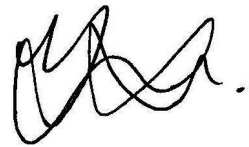
PET plastic boxes with 12 cups of 1000 doses

PET plastic boxes with 12 cups of 2500 doses

PET plastic boxes with 12 cups of 5000 doses

PET plastic boxes with 12 cups of 10 000 doses

Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 14 December 2022