1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND Clone 30 live lyophilisate for oculonasal suspension/use in drinking water for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Newcastle disease virus, strain Clone 30, live: ≥ 6.0 $\log_{10}$ ELD_{50}*
* ELD_{50} = Embryo Lethal Dose 50 %

Excipients:

Qualitative composition of excipients and other constituents
Sorbitol
Hydrolysed gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate
Water for injections

Lyophilisate:
Vials: white/off-white coloured pellet.
Cups: white/off-white and predominantly spherical shaped.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and turkeys.

3.2 Indications for use for each target species

For the active immunisation of chickens and turkeys to reduce mortality and clinical signs resulting from infection with Newcastle disease (but for use in turkeys, see comments in section 3.9).

Onset of immunity: 2 weeks.
Duration of immunity: 6 weeks in chickens, 4 weeks in turkeys.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Sick or weak birds will not develop adequate immunity following vaccination.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system.

Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

The vaccine virus may spread to susceptible, unvaccinated birds.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The vaccine virus can cause conjunctivitis in humans.
Wash and disinfect hands after use.
When spraying the vaccine, to avoid hay-fever like reactions in some individuals, personal protective equipment consisting of well-fitting masks to appropriate EU standards or better and eye protection to appropriate EU standards must be worn by the operator and staff.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens and turkeys:

Very common (>1 animal / 10 animals treated):	Respiratory signs[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Head shake - behavioural disorder[1, 2]

[1] The reaction following primary vaccination is usually mild. Symptoms may occur 4 - 7 days post vaccination and will usually disappear within 2 weeks.
[2] Slight.

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 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:
This vaccine should not be used in birds in lay, except in an emergency. On the basis of experience with this vaccine, emergency vaccination during lay is not expected to have a negative influence on egg production when administered to animals that have been previously vaccinated with live and inactivated Newcastle disease vaccine.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with the live infectious bronchitis Ma5 vaccine and live rhinotracheitis (strain 11/94) vaccines by Intervet.

Safety and/or efficacy data are available which demonstrate that this vaccine can be administered at least 7 days before the administration of infectious bursal disease vaccine (strain D78).

Vaccines which target non respiratory diseases (such as Marek's disease vaccines) may be administered with this vaccine provided that each of the vaccines is administered using the recommended route and the recommended doses.

Safety and efficacy data are available which demonstrate that Innovax-ILT (in chicks of one day of age only) can be administered on the same day, but not mixed with this vaccine.

Safety and efficacy data are available which demonstrate that this vaccine can be administered, but not mixed to day-old chicks that are vaccinated either by the subcutaneous route or to day-old chicks that have been vaccinated by the *in ovo* route with Innovax-ND-IBD.

Safety and efficacy data are available which demonstrate that this vaccine can be administered, but not mixed to day-old chicks that are vaccinated either by the subcutaneous route or to day-old chicks that have been vaccinated by the *in ovo* route with Innovax-ND-ILT.

No information is available on the safety and efficacy of the vaccine when used with any other vaccines 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

The vaccine can be administered by oculonasal use (instillation (dropping) into the eyes and nares, coarse spray) or in drinking water use. For instillation into the eyes and nares, use Nobilis Diluent Oculo Nasal.

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.

Chickens:
The vaccine can be administered to 1-day old chicks and older chickens by coarse spray or by the intranasal/ocular route of administration. The vaccine can be administered to 7-day and older chicks by drinking water.

Turkeys:
The vaccine has been shown to be efficacious when administered in the drinking water to antibody free turkeys of 2 weeks of age. Evidence for the safe use of this vaccine in turkeys is limited but field experience indicates that the vaccine may be safely administered to turkeys from 1 - 2 weeks of age via drinking water or coarse spray routes of administration.

Drinking water
When administering the vaccine by drinking water use cool, clean water supplemented with 2 grams of skimmed milk powder or 50 ml of liquid skimmed milk per litre to dissolve the vaccine, as it is known that this will make the virus retain its activity.

Reconstitution of vaccine:
The vials should be opened under water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. All containers used should be clean and free from any traces of detergent or disinfectant. Mix thoroughly with a clean stirrer, ensuring that all vials or cups used are emptied. After reconstitution the suspension looks clear.
Offer to birds immediately.

Use clean cold water, which is free of iron and chlorine. Where water sanitisers are used consult MSD Animal Health technical staff. Chlorine at levels as low as 1 ppm is known to have a detrimental effect on vaccine virus stability, therefore the use of liquid skimmed milk is recommended to prolong the life of the virus. By adding 2 grams skimmed milk powder per litre water the virus retains its activity much longer. This may be added to the water at the rate of 500 ml (approximately 1 pint) per 10 litres of water. After mixing well, the solution should be allowed to stand for 15 - 30 minutes before adding the vaccine. Only skimmed milk should be used, as the fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

Ensure uptake of all the vaccine medicated water in 2 hours. Depending on the weather conditions, it may be advisable to deprive the birds of water prior to vaccination. A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergents and disinfectants. Dissolve 1 000 doses in as many litres of water as the age of the birds in days, to a maximum of 40 litres.

The vaccine should be given in the early morning as this is the main period of drinking or the cool period on a hot day. When vaccinating larger flocks, it is advisable to start by dissolving only part of the vaccine. If vaccine is administered through a central water supply or a proportioner, great care should be taken. For numbers of birds between standard dosages, the next higher dosage should be chosen.

Volumes of water for reconstitution of vaccine:
The volume of water for reconstitution depends on the age of the birds and the management practice.

Simple drinking troughs and fountains:
The following are guidelines:
Dissolve 1 000 doses in as many litres of water as the age of the birds in days, to a maximum of 40 litres. Where the number of birds is between the standard dosages, the next higher dosage should be used.

Nipple Drinkers: Drinker line management is known to have a significant effect on the viability of live vaccine virus. The vaccine virus can deteriorate very rapidly and it is essential to ensure that all birds received the correct dose.
Special care should be observed concerning the method of administration. For example, small header tanks may require recharging with medicated water several times during a 1 - 2 hour period.

Administration:
Water should be withheld before vaccination. For recommendations see below under ”Management”. Ensure that all medicated water is consumed within 1 - 2 hours. Turn on mains water when all the vaccine water has been consumed. Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat.

Management:
Great care should be taken to ensure that all birds receive a full dose of vaccine when the product is administered. The following points have been found to improve vaccine "take":

1. Water withholding should be kept to a minimum. Approximately half an hour is all that is required if the following management techniques are used.
2. Try to vaccinate at a time when birds are likely to be drinking, e.g. when food is in the food tracks.
3. Turn the lights down low when the water is turned off. For bell drinkers, go round the house emptying and cleaning the drinkers during the half-hour lights low period. Mix up the vaccine according to the recommendations, and towards the end of the half-hour water withholding period, go round all the drinkers filling each with water containing vaccine. Leave the house and turn the light up. The increased light intensity will stimulate the birds to look for water and food. Therefore, it is important that food is available or the birds will not be interested in drinking. In some cases, it helps to run food tracks at the time the light intensity is increased.

For nipple lines a substantial volume of residual water may remain in the lines after the half-hour water withholding/dark period. It is advisable to drain the lines and prime with vaccine loaded water before allowing the birds to have access to the drinker lines. Mix up the vaccine and apply to the header tank(s). Calculate the volume of water that is left in the tank below the outlet valve and make sure you add extra vaccine to this volume of water. For example, if 10 litres remain below the outlet pipe and you are using 10 litres/1 000 birds to vaccinate, add one extra vial of vaccine when mixing up vaccine for that tank. The use of this extra vaccine is important.
4. Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination and will be less stressful to the birds. Performance should therefore be less adversely affected.

Coarse spray vaccination of day-old chicks:
This technique has been developed for use in very young chicks. 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 1 000 doses is suggested. The vaccine suspension should be spread evenly over the birds, at a distance of 30 - 40 cm (12 - 16”), preferably when the birds are sitting together in dim light. If applicable, reduce or stop ventilation to prevent loss of spray.

For further information on use of a vaccine in specific circumstances consult MSD Animal Health technical staff.

Instillation into the eyes and nares:
Reconstitute the vaccine with the appropriate amount of a suitable solvent and administer by means of the standardised dropper (of which the droplet size is known and consistent). The amount of solvent required for eye- or nare-drop administration depends on the number of doses and the droplet size, but approximately 35 ml per 1 000 doses is used. One drop should be applied into one nare or one eye. Ensure that the intranasal drop is inhaled before freeing the bird. For eye- or nare-drop administration, use Nobilis Diluent Oculo Nasal.

Vaccination programme:
The optimal time and method of administration depend largely upon the local situation.

Revaccination:
If prolonged immunity is required, the chickens can be revaccinated every 6 weeks and turkeys every 4 weeks.

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

The reactions seen after administration of an overdose are generally similar to the reactions seen after a single dose (but in rare cases the reactions may be somewhat more pronounced).

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 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.
Protect from light.
Keep the vials/cups in the outer carton.

5.4 Nature and composition of immediate packaging

Glass vials of 10 ml (hydrolytic glass type I) with halogenobutyl rubber stopper and aluminium cap.

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

Pack sizes:
Cardboard box with 1, 10 or 50 vials of 500 doses.
Cardboard box with 1, 10 or 50 vials of 1 000 doses.
Cardboard box with 1, 10 or 50 vials of 2 000 doses.
Cardboard box with 1, 10 or 50 vials of 2 500 doses.
Cardboard box with 1, 10 or 50 vials of 3 000 doses.
Cardboard box with 1, 10 or 50 vials of 5 000 doses.
Cardboard box with 1, 10 or 50 vials of 10 000 doses.
PET plastic box with 12 cups of 1 000 doses.
PET plastic box with 12 cups of 2 500 doses.
PET plastic box with 12 cups of 5 000 doses.
PET plastic box with 6 cups of 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.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/091/001

8. DATE OF FIRST AUTHORISATION

31/08/2004

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

13/03/2026

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).