SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis ND Clone 30 live

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	**per dose**
Live Newcastle disease virus, strain Clone	$30 \geq 6.0 \log_{10} ELD_{50}$*

For a full list of excipients, see section 6.1.

*ELD_{50} = 50% Egg Lethal Dose

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water.

Vials: white/off-white coloured pellet.
Cups: white/off white

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and turkeys

4.2 Indications for use, specifying the 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 4.9).

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

4.3 Contraindications

None

4.4 Special warnings for each target species

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.

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

The vaccine virus may spread to susceptible, unvaccinated birds.

4.5 Special precautions for use

i. Special precautions for use in animals

None

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

The vaccine virus can cause conjunctivitis in man.
Wash and disinfect hands after use.
When spraying the vaccine, to avoid hay-fever like reactions in some individuals, well-fitting masks to appropriate EU standards or better and eye protection to appropriate EU standards must be worn by the operator and staff.

4.6 Adverse reactions (frequency and seriousness)

The reaction following primary vaccination is usually mild. Some respiratory disturbances and slight head shaking may occur 4 - 7 days post vaccination; these symptoms will usually disappear within two weeks.

4.7 Use during pregnancy, lactation or lay

Nobilis ND Clone 30 should not be used in birds in lay, except in an emergency. On the basis of experience with Nobilis ND Clone 30 emergency, vaccination during lay is not expected to have a negative influence on the egg production when administered to animals that have been previously vaccinated with live and inactivated Newcastle disease vaccine.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrates 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 demonstrates that this vaccine can be administered 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 Nobilis Clone 30 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, Nobilis ND Clone 30.

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 (Nobilis ND Clone 30) when used with any other vaccine except the product 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.

4.9 Amounts to be administered and administration route

The vaccine can be administered by spray, by ocular or nasal instillation or through the drinking water. For the ocular/nasal instillation a special diluent, Diluent Oculo-Nasal, is available.

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.

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

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 spray routes of administration.

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

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 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 gram 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 1000 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:
1000 doses per litre per age in days up to a volume of 20 litres per 1000 doses. For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litres per 1000 doses. 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/1000 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.

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 1000 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.

Oculo-nasal administration

Reconstitute the vaccine with the appropriate amount of a suitable diluent and administer by means of the standardised dropper (of which the droplet size is known and consistent). 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.

For eye- or nose-drop administration Nobilis Diluent Oculo Nasal is available in a dropper in two dosage forms (1000 and 2500 doses).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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).

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI01AD06

To stimulate active immunity against Newcastle Disease Virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate

6.2 Incompatibilities

Do not mix with any other medicinal product apart from those detailed in section 4.8.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale

2 years at between +2°C and +8°C (following up to 2 years at -20°C storage by manufacturer).

Shelf life after reconstitution according to directions

Once reconstituted use within 2 hours.

6.4 Special precautions for storage

Keep out of the sight and reach of children.
Store at 2 °C - 8 °C. Do not freeze. Protect from light.
The vaccine should be used immediately after reconstitution.
Do not use after the expiry date stated on the label/carton.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

Vial of hydrolytic type I glass containing a freeze-dried pellet. The vial is closed with a halogenobutyl rubber stopper and sealed with an aluminium cap
Vials may contain 500, 1000, 2500, 5000 or 10000 doses.
Not all pack sizes may be marketed.

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

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5047

9. DATE OF FIRST AUTHORISATION

24 October 2005

10. DATE OF REVISION OF THE TEXT

May 2025

Approved 06 May 2025
Gavin Hall