SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro ND C131 Lyophilisate for suspension for chickens and turkeys.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each dose contains
Newcastle Disease Virus, live attenuated, strain clone 13-1 $10^{6.0}$ - $10^{7.2}$ EID_{50}
*EID_{50}= 50%-embryo infectious dose: the virus titre causing infection in 50% of the embryos inoculated with the virus.

Excipients:

Qualitative composition of excipients and other constituents
Disodium Phosphate Dihydrate
Sodium Dihydrogen Phosphate Dihydrate
Gelatine
Sucrose
Sorbitol

Appearance: white-beige pellet

3. CLINICAL INFORMATION

3.1 Target species

Chickens and turkeys.

3.2 Indications for use for each target species

Active immunisation of chickens and turkeys against Newcastle disease to reduce clinical signs and mortality.

Chickens:
Onset of immunity: 3 weeks after vaccination (7 days in seronegative chickens when vaccinated at 14 days of age).
Duration of immunity: 8 weeks after vaccination

Turkeys:
Onset of immunity: 2 weeks after vaccination
Duration of immunity: 8 weeks after vaccination

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
See also section 3.7

Maternally derived antibodies (MDA) may interfere with the development of a protective immune response following vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chickens:
The vaccine virus is excreted with faeces up to 12 days and may spread to susceptible animals by contact infection. However, ND negative contact animals do not show sero-conversion until 15 days after contact.

Turkeys:
The vaccine virus is excreted for less than 14 days after vaccination.
The vaccine virus may spread to susceptible non-vaccinated turkeys without inducing any clinical symptoms.

Transmission of the vaccine strain to ducks and geese is harmless. In pigeons slight pathological findings were observed in the respiratory tract, but no clinical symptoms occurred.

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

ND-virus can induce conjunctivitis upon contact to eyes. Therefore during spraying eye- and inhalation protection (**face mask/visors)** must be worn.
Upon contact of the veterinary medicinal product to eyes seek medical advice.
Wash and disinfect hands and equipment after application.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Common (1 to 10 animals / 100 animals treated):	Respiratory tract disorders* like cough and sneezing

*3 – 15 days after vaccination. This does not influence the performance of the birds. Severity and duration of adverse reactions are dependent on the (maternal) immune status as well as the general health condition of the chickens at the time point of vaccination.

Turkeys:
None.

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

Chickens:
Safety data demonstrate that layers can be vaccinated during the laying period according to the recommended vaccine schedule (see 3.9).

In non-primed birds ND-vaccine virus was found in the oviduct after 10-fold over dosage. No egg transmission is observed in laying birds after basic immunisation.

The safety of the veterinary medicinal product has not been established in breeders during lay.

Turkeys:
The safety of the veterinary medicinal product has not been established during lay.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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

Species	Vaccination age	Administration route
Chickens	from 1 day onwards	nebulisation
	from 14 days onwards	nebulisation, ocular use, in drinking water use
Turkeys	from 21 days onwards	in drinking water use

Ensure that the drinking water is cold, clean, non-chlorinated and free from detergents, disinfectants and metal ions.

- Remove sealing cap and stopper from vaccine container.
- Suspend the vaccine in the corresponding amount of water and mix carefully.
- Prepare only the amount of vaccine that can be administered within 2 hours.
- The vaccine is ready for use.

a) Ocular use (chickens)

The equipment used for eye drop application should be clean, free of detergents and disinfectants and should be used for vaccination purposes only.
For preparation of the vaccine use 34 ml of boiled and cooled drinking water per 1000 doses of vaccine.
Administer 1 droplet (corresponding to approximately 34 µl) into one eye of each chicken to be vaccinated by use of a pipette or dropper.

b) Nebulisation (chickens)

The amount of drinking water to be used for nebulisation depends on local and husbandry conditions.
After removing the stopper under water 1000 doses of vaccine are diluted as follows:

- 500 ml for 1000 chickens up to the 4th week of life
- 750 – 1000 ml for 1000 chickens after the 4th week of life.

The chickens are sprayed uniformly with a distance of 30 – 40 cm.
During and after vaccination ventilation should be switched off in order to avoid turbulences.

For primary vaccination during the 1st weeks of life a coarse spray having a droplet size of 100 µm and more should be used to avoid penetration into the lower parts of the respiratory tract and increased vaccination reactions.

c) In drinking water use (chickens and turkeys)

1. all equipment used for vaccination (tubes, drinkers etc.) are carefully cleaned and are free of detergents and disinfectants.
2. Estimate the amount of water according to the number of birds to be vaccinated (see 5.) Only cold clean water of drinking water quality should be used.
   The addition of skimmed milk powder (2 – 4 g/l water) or skimmed milk (20 – 40 ml/l water) may positively influence the stability of the vaccine. Skimmed milk powder or skimmed milk must be carefully mixed with the water before dilution of the vaccine.
3. Remove aluminium-cap. Open the stopper of vaccine bottle under water and dilute the contents completely.
4. For easy handling the vaccine should be prepared in a small container (about 1 litre). Rinse the vial carefully and empty it completely. The vaccine suspension is then diluted in a larger vessel (5 – 10 l) and mixed well again. The complete content of the vaccine vials should be used for one flock or drinking water system only. Splitting of the diluted vaccine may lead to dosage errors.
5. To the vaccine suspension fresh cold water is added to a final volume that will be consumed by the birds within 1 – 2 hours. In case of doubt the uptake of water should be established the day before vaccination.
6. Drinker lines still filled with water must be drained before application of the vaccine suspension. The vaccine should be consumed within 2 hours. Since drinking behaviour of birds is varying it may be necessary to withdraw the drinking water for 2-3 hours before vaccination to ensure that all birds will drink during the vaccination phase. Every bird should receive an adequate dose of the vaccine.

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

Chickens:
Severity and duration of adverse reactions after the administration of a 10-fold dose are dependent on the (maternal) immune status as well as the general health condition of the chickens at the time point of vaccination.

Turkeys:
None.

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

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI01AD06
Pharmacotherapeutic group: Immunologicals, immunologicals for aves, domestic fowl, live viral vaccines, Newcastle disease virus/paramyxovirus
The component of the vaccine is a live, lentogenic ND-strain which stimulates active immunity against Newcastle Disease.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any substance other than water and skimmed milk or skimmed milk powder.
Ensure that the drinking water is cold, clean, non-chlorinated and free from detergents, disinfectants and metal ions.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after reconstitution according to directions: 2 hours
The complete content of opened containers should be used at once.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Crimp vials made of glass type I (Ph.Eur.) with type I rubber closure.
The vials are sealed with aluminium tear-off crimp caps.

The vaccine is available in the following packaging sizes:
Box with 1 vial with 2000 doses
Box with 10 vials with 2000 doses
Box with 1 vial with 5000 doses
Box with 10 vials with 5000 doses

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

7. MARKETING AUTHORISATION NUMBER

Vm 00879/3031

8. DATE OF FIRST AUTHORISATION

22 August 2007

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

November 2023

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).

Approved 10 November 2023