PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Cardboard box with 1 or 10 vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro ND C131
Lyophilisate for suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose contains Newcastle Disease Virus, live attenuated, strain clone 13-1
$10^{6.0}$ - $10^{7.2}$ EID_{50}

3. PACKAGE SIZE

10x 2,000, 10x 5,000 doses
1x 2,000, 1x 5,000 doses

4. TARGET SPECIES

Chickens and turkeys.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For drinking water, ocular and nebulisation use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days

8. EXPIRY DATE

EXP {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. .
Do not freeze.
Protect from light.

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

Elanco GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5099

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro ND C131 Lyophilisate for suspension.

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

2000, 5000 doses live NDV, strain clone 13-1

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}
Shelf life after reconstitution according to directions: 2 hours.

5. ROUTE(S) OF ADMINISTRATION

For drinking water, ocular and nebulisation use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro ND C131 Lyophilisate for suspension for chickens and turkeys.

2. COMPOSITION

Active substance:

Each dose contains:

Newcastle Disease Virus, live attenuated, strain clone 13-1 $10^{6.0}$ - $10^{7.2}$ EID_{50}*

Appearance: white-beige pellet

*EID_{50}= 50%-embryo infectious dose: the virus titre causing infection in 50% of the embryos inoculated with the virus.

3. TARGET SPECIES

Chickens and turkeys.

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

Special warnings:
Vaccinate healthy animals only.
Maternally derived antibodies (MDA) may interfere with the development of a protective immune response following vaccination.

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. During this time, the contact of immunodepressed and unvaccinated chicken with vaccinated chicken should be avoided.
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.

Laying birds:

Chickens:

Safety data demonstrate that layers can be vaccinated during the laying period according to the recommended vaccine schedule (see ”Dosage for each species, routes and method of administration”). 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.

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.

Overdose :

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.

Major incompatibilities:

Do not mix with any substances 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.

7. 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 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.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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 drinking 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 of 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)

- All equipment used for vaccination (tubes, drinkers etc.) are carefully cleaned and are free of detergents and disinfectants.

- 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.
- Remove aluminium-cap. Open the stopper of vaccine bottle under water and dilute the contents completely.
- 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.
- 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.

- 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.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
Shelf life after reconstitution according to directions: 2 hours.
The complete content of opened containers should be used at once.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5099

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany
Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:
Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, 27472 Cuxhaven

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription

For animal treatment only.

Gavin Hall

Approved: 22 April 2026