

## **A. LABELLING**

**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 for chickens and turkeys.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose contains Newcastle Disease Virus, live attenuated, strain clone 13-1  
 $10^{6.0} - 10^{7.2}$  EID<sub>50</sub>

**3. PHARMACEUTICAL FORM**

Lyophilisate for suspension

**4. PACKAGE SIZE**

10 x 500, 10 x 1,000, 10 x 2,500, 10 x 5,000, 10 x 10,000 doses  
1 x 500, 1 x 1,000, 1 x 2,500, 1 x 5,000, 1 x 10,000 doses

**5. TARGET SPECIES**

Chickens and turkeys.

**6. INDICATION(S)**

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

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
For drinking water, ocular and nebulisation use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once reconstituted use within 2 hours.

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only. To be supplied only on veterinary prescription.

**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**

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 00879/4186

**17. MANUFACTURER’S BATCH NUMBER**

Batch{number}

**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. ACTIVE SUBSTANCE(S)**

Live NDV, strain clone 13-1

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

500, 1000, 2500, 5000, 10 000 doses

**4. ROUTE(S) OF ADMINISTRATION**

For drinking water, ocular and nebulisation use.

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Batch {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## PACKAGE LEAFLET

### Directions for Use

AviPro ND C131  
Lyophilisate for suspension for chickens and turkeys.

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

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

Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, 27472 Cuxhaven

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro ND C131 Lyophilisate for suspension for chickens and turkeys.

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:

Each dose contains:

Newcastle Disease Virus, live attenuated, strain clone 13-1  $10^{6.0} - 10^{7.2}$  EID<sub>50</sub>\*

Lyophilisate for suspension.

Appearance: off-white pellet

\*EID<sub>50</sub> = 50%-embryo infectious dose: the virus titre causing infection in 50% of the embryos inoculated with the virus.

#### 4. INDICATION(S)

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. ADVERSE REACTIONS

### Chickens:

Slight reactions of the respiratory tract (coughing or sneezing) 3 – 15 days after vaccination have been reported commonly during clinical studies. 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 and turkeys.

## 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

### **Mode of application:**

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 consumed 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 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 4<sup>th</sup> week of life
- 750 – 1000 ml for 1000 chickens after the 4<sup>th</sup> 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 1<sup>st</sup> 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.
- The water present in the drinking water should be consumed before vaccination. Pipes 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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Not applicable.

## **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.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Vaccinate healthy birds only.

See also section “lay”.

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

Special precautions for use in animals:

### **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 nebulisation eye- and inhalation protection (**face mask/visors**) must be worn. Upon contact of the product to eyes seek medical advice.

**Wash and disinfect hands after application.**

### Lay:

#### **Chickens:**

Safety data demonstrate that layers can be vaccinated during the laying period according to the recommended vaccine schedule (see 8). 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 (symptoms, emergency procedures, 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.

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.

**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**

September 2020

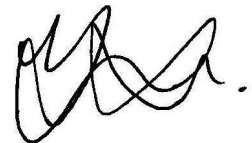
**15. OTHER INFORMATION**

For animal treatment only.

The vaccine is available in the following packaging sizes:

- Box with 1 vial with 500 doses
- Box with 10 vials with 500 doses
- Box with 1 vial with 1000 doses
- Box with 10 vials with 1000 doses
- Box with 1 vial with 2500 doses
- Box with 10 vials with 2500 doses
- Box with 1 vial with 5000 doses
- Box with 10 vials with 5000 doses
- Box with 1 vial with 10000 doses
- Box with 10 vials with 10000 doses

Not all pack sizes may be marketed.



Approved: 17 March 2022