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:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension
Appearance: off-white pellet

4. CLINICAL PARTICULARS

4.1 Target species
Chickens and turkeys.

4.2 Indications for use,specifying the 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

4.3 Contraindications
None.

4.4 Special warnings for each target species
Vaccinate healthy birds only.
See also section 4.7

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

4.5 Special precautions for use

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. 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 product to eyes seek medical advice.
Wash and disinfect hands and equipment after application.

4.6 Adverse reactions (frequency and seriousness)
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)

4.7 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 4.9.).

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.

4.8 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.

4.9 Amounts to be administered and administration route

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 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 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. 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.

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

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.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peptone
Magnesium sulphate
Sucrose
Gelatine

6.2 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.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale	1 year
Shelf life after reconstitution according to directions	2 hours

The complete content of opened containers should be used at once.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Crimp vials made of glass type I (Ph.Eur.) with Chlorobutyl-Elastomer 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 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Lohmann Animal Health GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.