SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IB – ND C131 Lyophilisate for oculonasal suspension/use in drinking water for chicken

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Each dose contains

- Infectious Bronchitis virus, live attenuated, strain Massachusetts H120 $10^{3.4} – 10^{4.8}$ EID_{50}*
- Newcastle Disease virus, live attenuated, strain clone 13-1 $10^{5.5} – 10^{7.2}$ 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

Chicken (broiler).

3.2 Indications for use for each target species

For active immunisation of chicken (broiler) against Newcastle Disease to reduce clinical signs and mortality.
For active immunisation of chicken (broiler) against Infectious Bronchitis in order to reduce the detrimental effect resulting from the infection by avian infectious bronchitis virus, serotype Massachusetts on the ciliary activity, which may be manifested in respiratory clinical signs.

Onset of immunity (IBV): 3 weeks after vaccination
Onset of immunity (NDV): 2 weeks after vaccination

Duration of immunity: 8 weeks after vaccination

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the IBV vaccine strain at least up to 21 days and the NDV vaccine strain for less than 15 days. Both vaccine strains can spread to unvaccinated chickens. Mild respiratory symptoms (like after vaccination) may occur.

Transmission of the NDV vaccine strain to ducks, turkeys and geese does not pose a safety concern. In pigeons, slight pathological findings were observed in the respiratory tract, but no clinical symptoms occurred. Spread to other susceptible species should be avoided.

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

NDV can induce conjunctivitis upon contact to eyes.
Personal protective equipment consisting of eye-, inhalation protection (face mask/visors) and gloves should be worn when handling the veterinary medicinal product.
Avoid any contamination by splashing or spillage.
Wash and disinfect hands and equipment after use.

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken (broiler)

For spray administration:

Rare (1 to 10 animals / 10,000 animals treated):	Respiratory tract disorders* like cough, respiratory sound and dyspnoea

For in drinking water use:

Common (1 to 10 animals / 100 animals treated):	Respiratory tract disorders* like cough, nasal discharge and dyspnoea

*Vaccination may induce mild and transient signs that may persist for up to three days. Transient impaired ciliary activity was observed in laboratory safety studies.

The characteristics of adverse reactions may depend on the (maternal) immune status of the chickens at the time point of vaccination.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

For spray administration (from 1st day of life onwards) and for administration via drinking water (from 7th day of life onwards).
One dose of the vaccine should be administered per animal.

Spray administration

The amount of drinking water to be used for spraying 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 vaccination 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.

In drinking water use

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 l). 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)

Apart from the respiratory symptoms mentioned in section 3.6, transient complete or high ciliostasis has been observed following administration of a ten-fold dose.

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

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

Infectious bronchitis virus:
ATCvet code: QI01AD07
Pharmacotherapeutic group: immunologicals, immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bronchitis virus

Newcastle disease virus:
ATCvet code: QI01AD06
Pharmacotherapeutic group: immunologicals, immunologicals for aves, domestic fowl, live viral vaccines, Newcastle disease virus/paramyxovirus

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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

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

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:
Cardboard box with 1 vial with 2000 doses
Cardboard box with 10 vials with 2000 doses
Cardboard box with 1 vial with 5000 doses
Cardboard 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 products 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 GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD month YYYY

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

DD month YYYY

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).

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
cardboard box with 1 or 10 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IB – ND C131 Lyophilisate for oculonasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains

- Infectious Bronchitis virus, live attenuated, strain Massachusetts H120 $10^{3.4} – 10^{4.8}$ EID_{50}
- Newcastle Disease virus, live attenuated, strain clone 13-1 $10^{5.5} – 10^{7.2}$ EID_{50}

3. PACKAGE SIZE

10x 2000 doses, 10x 5000 doses
1x 2000 doses, 1x 5000 doses

4. TARGET SPECIES

Chicken (broiler).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For spray administration and in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: 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 NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IB – ND C131

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2000, 5000 doses
Live NDV, strain clone 13-1
Live IBV, strain Massachusetts H120

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro IB – ND C131 Lyophilisate for oculonasal suspension/use in drinking water for chickens

2. Composition

Active substances:
Each dose contains

- Infectious Bronchitis virus, live attenuated, strain Massachusetts H120 $10^{3.4} – 10^{4.8}$ EID_{50}*
- Newcastle Disease virus, live attenuated, strain clone 13-1 $10^{5.5} – 10^{7.2}$ EID_{50}*

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

Appearance: white-beige pellet

3. Target species

Chicken (broiler).

4. Indications for use

For active immunisation of chicken (broiler) against Newcastle Disease to reduce clinical signs and mortality.
For active immunization of chicken (broiler) against Infectious Bronchitis in order to reduce the detrimental effect resulting from the infection by avian infectious bronchitis virus, serotype Massachusetts on the ciliary activity, which may be manifested in respiratory clinical signs.

Onset of immunity (IBV): 3 weeks after vaccination
Onset of immunity (NDV): 2 weeks after vaccination

Duration of immunity: 8 weeks after vaccination

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Vaccinated chickens may excrete the IBV vaccine strain at least up to 21 days and the NDV vaccine strain for less than 15 days. Both vaccine strains can spread to unvaccinated chickens. Mild respiratory symptoms (like after vaccination) may occur.

Transmission of the NDV vaccine strain to ducks, turkeys and geese does not pose a safety concern. In pigeons, slight pathological findings were observed in the respiratory tract, but no clinical symptoms occurred. Spread to other susceptible species should be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
NDV can induce conjunctivitis upon contact to eyes.
Personal protective equipment consisting of eye-, inhalation protection (face mask/visors) and gloves should be worn when handling the veterinary medicinal product.
Avoid any contamination by splashing or spillage.
Wash and disinfect hands and equipment after use.

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Laying birds:
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:
Apart from the respiratory symptoms mentioned in section 3.6, transient complete or high ciliostasis has been observed following administration of a ten-fold dose.

Special restrictions for use and special conditions for use:
Official control authority batch release is required for this product.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chicken (broiler)

For spray administration:

Rare (1 to 10 animals / 10,000 animals treated):	Respiratory tract disorders* like cough, respiratory sound and dyspnoea

For in drinking water use:

Common (1 to 10 animals / 100 animals treated):	Respiratory tract disorders* like cough, nasal discharge and dyspnoea

*Vaccination may induce mild and transient signs that may persist for up to three days. Transient impaired ciliary activity was observed in laboratory safety studies.

The characteristics of adverse reactions may depend on the (maternal) immune status of the chickens at the time point of vaccination.

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, routes and method of administration

For spray administration (from 1st day of life onwards) and for administration via drinking water (from 7th day of life onwards).
One dose of the vaccine should be administered per animal.

9. Advice on correct administration

Spray administration

The amount of drinking water to be used for spraying 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 vaccination 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.

In drinking water use

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 l). 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.

10. Withdrawal periods

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 frost.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after reconstitution according to directions: 2 hours

12. Special precautions for disposal

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 applicable national collection systems. 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

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

Česká republika
PV.CZE@elancoah.com

Deutschland
PV.DEU@elancoah.com

España
PV.ESP@elancoah.com

France
PV.FRA@elancoah.com

Italia
PV.ITA@elancoah.com

Magyarország
PV.HUN@elancoah.com

Nederland
PV.NLD@elancoah.com

Österreich
PV.AUT@elancoah.com

Polska
PV.POL@elancoah.com

Portugal
PV.PRT@elancoah.com

România
PV.ROU@elancoah.com

Manufacturer responsible for batch release:
Lohmann Animal Health GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany