

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Precise

AviPro IBD LC-75 (DK)

Lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

Infectious bursal disease virus, strain LC 75, live: $10^{3.0}$ - $10^{4.5}$ EID₅₀*.

*EID₅₀ = 50 % egg-infectious dose: the virus titre required to cause infection in 50 % of the inoculated embryos

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate dihydrate
Lactose monohydrate
Potassium dihydrogen phosphate
Skim milk powder

Rose to red brown lyophilisate

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For active immunisation of susceptible chickens from 7 days old against infectious bursal disease (IBD/Gumboro).

The vaccine reduces clinical signs of IBD and severe bursal lesions.

Onset of immunity: 2 weeks after vaccination

Duration of immunity: 4 weeks after vaccination (demonstrated by challenge), antibodies may last up to 15 weeks.

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 vaccine strain for at least 9 days following vaccination. Special precautions should be taken to avoid spreading of the vaccine strain to laying hens.

To reduce infection pressure before the onset of immunity, litter should be removed, and chicken housing cleaned between rearing cycles.

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

Live attenuated viral vaccine: do not spray or spill. Wash and disinfect hands and equipment after vaccinating.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion ¹
Rare (1 to 10 animals / 10 000 animals treated):	Bursa of Fabricius degeneration ²

¹Of moderate intensity, seen on day 7 post vaccination. Lymphocyte repopulation occurs after day 7 post vaccination.

²Mild necrosis by day 28 post 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

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

In drinking water use: One dose (min. $10^{3.0}$ EID₅₀) should be administered per animal from the age of 7 days onwards.

The determination of the vaccination date is depending on a number of factors including status of maternal antibodies, type of bird, infection pressure, housing and management conditions.

Maternally derived antibodies (MDA) potentially interfere with the take of live IBD vaccines. The optimum age for vaccination therefore depends on both, the level of MDA against IBD in the flock and the capability of the vaccine to take in face of these MDA ("break-through-titre"). A high homogeneity of the flock MDA levels is important to define the timing of vaccination and guarantees

the better take of the vaccine. To predict the age, when MDA have sufficiently decreased to allow effective vaccination, it is advised to test serum samples of at least 24 chicks by serology and apply the “Deventer Formula” for intermediate vaccines. For chicks from fully vaccinated or field virus infected breeders this may be at 14 days or more. Serologically negative birds may be vaccinated from day 7.

A further vaccination 7 days after the first may be necessary particularly in flocks where antibody levels vary widely between birds (i.e. CV greater than 30 %), or stock originates from different sources.

Broilers:

- with no maternal antibodies – from 7 days of age
- with maternal antibodies – from 14 days of age

Layers/Breeders:

- with no maternal antibodies – from 7 days of age
- with maternal antibodies – from 3 - 4 weeks of age

Dosage and administration:

Drinking water application:

- Determine the number of vaccine doses and amount of water (see below) required. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.
- Make sure that all conduit pipes, tubing, troughs, drinkers etc are thoroughly clean and free of any trace of disinfectants, detergents etc.
- Ensure that the drinking water is cold, clean, and free from detergents and disinfectants to ensure the viability of the vaccine. Use only fresh water preferably non-chlorinated and free from metal-ions. Low-fat skimmed milk powder (i.e. < 1 % fat) may be added to the water (2 – 4 grams per litre) or skimmed milk (20 – 40 ml per litre of water) to improve the water quality and to increase the stability of the virus. This, however, has to be done 10 minutes prior to reconstitution of the vaccine.
- Open the vaccine ampoule under water and reconstitute contents thoroughly. Care should be taken to empty the ampoule and its top completely by rinsing them in water.
- Allow water to be consumed so that levels in drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water. If water is still present, drain lines before applying vaccine.
- Apply vaccine over (up to) 2 hours, ensuring that all birds drink during this time. Birds drinking behaviour varies, it may be necessary to withhold water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period.
- The aim is to give every bird one dose of vaccine.
- Ideally vaccine should be administered in the volume of water consumed by the birds in up to 2 hours. As a general rule, apply reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 10 litres would be needed for 1 000, 10 days old chickens. Under hot climates or with heavy breeds this amount may have to be increased up to a maximum of 40 litres per 1 000 birds. If in doubt, measure water intake the day before administering vaccine.
- Administer the reconstituted vaccine to birds immediately. Make sure that birds do not have access to unmedicated water during vaccination.

- The contents of opened bottles should be used all at once.
- Only the volume of vaccine should be prepared which can be applied within 2 hours.

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

No other signs have been observed as described under “Adverse events” 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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI01AD09

The active ingredient of the vaccine is a live attenuated infectious bursal disease-virus strain LC 75 which stimulates active immunity against IBD-virus.

The strain is an intermediate one with an average score of bursal lesion of 0.6 at 28 days post vaccination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 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 direct sunlight. Protect the reconstituted vaccine from direct sunlight and temperatures of above 25 °C.

5.4 Nature and composition of immediate packaging

Nature of immediate packaging elements:

- type I glass vial
- type I rubber closure
- aluminium cap

The following pack sizes are registered:
1 x 1 000 / 2 500 / 5 000 / 10 000 doses

10 x 1 000 / 2 500 / 5 000 / 10 000 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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

To be completed nationally.

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

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Precise
Lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains infectious bursal disease virus, strain LC 75, live: $10^{3.0}$ - $10^{4.5}$ EID₅₀.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Do not freeze. Protect from direct sunlight.
Protect the reconstituted vaccine from direct sunlight and temperatures of above 25 °C.

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS
--

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
--

AviPro Precise

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 000 / 2 500 / 5 000 / 10 000 doses live IBDV, LC 75

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro Precise
Lyophilisate for use in drinking water

2. Composition

Each dose contains:

Active substances:

Infectious bursal disease virus, strain LC 75, live: $10^{3,0}$ - $10^{4,5}$ EID₅₀*.

*EID₅₀ = 50 % egg- infectious dose: the virus titre that is required in order to cause an infection in 50 % of the embryos

Rose to red brown lyophilizate

3. Target species

Chickens

4. Indications for use

For active immunisation of susceptible chickens from 7 days old against infectious bursal disease (IBD/Gumboro).

The vaccine reduces clinical signs of IBD and severe bursal lesions.

Onset of immunity: 2 weeks after vaccination

Duration of immunity: 4 weeks after vaccination (demonstrated by challenge), antibodies may last up to 15 weeks.

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 vaccine strain for at least 9 days following vaccination. Special precautions should be taken to avoid spreading of the vaccine strain to laying hens.

To reduce infection pressure before the onset of immunity, litter should be removed, and chicken housing cleaned between rearing cycles.

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

Live attenuated viral vaccine: do not spray or spill. Wash and disinfect hands and equipment after vaccinating.

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

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:

No other signs have been observed as described under “Adverse events” following administration of a ten-fold dose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

7. Adverse events

Chickens:

Very common (> 1 animal / 10 animals treated):
Bursa of Fabricius lymphocyte depletion ¹
Rare (1 to 10 animals / 10 000 animals treated):
Bursa of Fabricius degeneration ²

¹Of moderate intensity, seen on day 7 post vaccination. Lymphocyte repopulation occurs after day 7 post vaccination.

²Mild necrosis by day 28 post 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: {national system detail}.

8. Dosage for each species, routes and method of administration

In drinking water use: One dose (min. $10^{3.0}$ EID₅₀) should be administered per animal from the age of 7 days onwards.

The determination of the vaccination date is depending on a number of factors including status of maternal antibodies, type of bird, infection pressure, housing and management conditions. Maternally derived antibodies (MDA) potentially interfere with the take of live IBD vaccines. The optimum age for vaccination therefore depends on both, the level of MDA against IBD in the flock and the capability of the vaccine to take in face of these MDA (“break-through-titre”). A high

homogeneity of the flock MDA levels is important to define the timing of vaccination and guarantees the better take of the vaccine. To predict the age, when MDA have sufficiently decreased to allow effective vaccination, it is advised, to test serum samples of at least 24 chicks by serology and apply the “Deventer Formula” for intermediate vaccines. For chicks from fully vaccinated or field virus infected breeders this may be at 14 days or more. Serologically negative birds may be vaccinated from day 7.

A further vaccination 7 days after the first may be necessary particularly in flocks where antibody levels vary widely between birds (i.e. CV greater than 30 %), or stock originates from different sources.

Broilers:

- with no maternal antibodies – from 7 days of age
- with maternal antibodies – from 14 days of age

Layers/Breeders:

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- with maternal antibodies – from 3 - 4 weeks of age

Dosage and administration:

Drinking water application:

- Determine the number of vaccine doses and amount of water (see below) required. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.
- Make sure that all conduit pipes, tubing, troughs, drinkers etc are thoroughly clean and free of any trace of disinfectants, detergents etc.
- Ensure that the drinking water is cold, clean, and free from detergents and disinfectants to ensure the viability of the vaccine. Use only fresh water preferably non-chlorinated and free from metal-ions. Low-fat skimmed milk powder (i.e. < 1 % fat) may be added to the water (2 – 4 grams per litre) or skimmed milk (20 – 40 ml per litre of water) to improve the water quality and to increase the stability of the virus. This, however, has to be done 10 minutes prior to reconstitution of the vaccine.
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- Allow water to be consumed so that levels in drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water. If water is still present, drain lines before applying vaccine.
- Apply vaccine over (up to) 2 hours, ensuring that all birds drink during this time. Birds drinking behaviour varies, it may be necessary to withhold water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period.
- The aim is to give every bird one dose of vaccine.
- Ideally vaccine should be administered in the volume of water consumed by the birds in up to 2 hours. As a general rule, apply reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 10 litres would be needed for 1 000, 10 days old chickens. Under hot climates or with heavy breeds this amount may have to be increased up to a maximum of 40 litres per 1 000 birds. If in doubt, measure water intake the day before administering vaccine.

- Administer the reconstituted vaccine to birds immediately. Make sure that birds do not have access to unmedicated water during vaccination.
- The contents of opened bottles should be used all at once.
- Only the volume of vaccine should be prepared which can be applied within 2 hours.

9. Advice on correct administration

Avoid stress before, during and after vaccination.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the reach and sight of children.

Store and transport refrigerated (2 °C – 8 °C) Do not freeze. Protect from direct sunlight.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours
Protect the reconstituted vaccine from direct sunlight and temperatures of above 25 °C.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorization numbers:

The following pack sizes are registered:
1 x 1 000/ 2 500/ 5 000/ 10 000 doses
10 x 1 000/ 2 500/ 5 000/ 10 000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
To be completed nationally.

België/Belgique/Belgien

{Nom/Naam/Name}
{Adresse/Adres/Anschrift}
BE-0000 {Localité/Stad/Stadt}
Tél/Tel: + {N° de téléphone/Telefoonnummer/
Telefonnummer}
<{E-mail}>

Lietuva

{pavadinimas}
{adresas}
LT {pašto indeksas} {miestas}
Tel: + {telefono numeris}
<{E-mail}>

Република България

{Наименование}
{Адрес}
BG {Град} {Пощенски код}
Тел: + {Телефонен номер}
<{E-mail}>

Luxembourg/Luxemburg

{Nom}
{Adresse}
L-0000 {Localité/Stad}
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{E-mail}>

Česká republika

{Název}
{Adresa}
CZ {město}
Tel: + {telefonní číslo}
<{E-mail}>

Magyarország

{Név}
{Cím}
HU-0000 {Város}
Tel.: + {Telefonszám}
<{E-mail}>

Danmark

{Navn}
{Adresse}
DK-0000 {by}
Tlf.: + {Telefonnummer}
<{E-mail}>

Malta

{Isem}
{Indirizz}
MT-0000 {Belt/Raħal}
Tel: + {Numru tat-telefon}
<{E-mail}>

Deutschland

{Name}
{Anschrift}
DE-00000 {Stadt}
Tel: + {Telefonnummer}
<{E-mail}>

Nederland

{Naam}
{Adres}
NL-0000 XX {stad}
Tel: + {Telefoonnummer}
<{E-mail}>

Eesti

(Nimi)
(Aadress)
EE - (Postiindeks) (Linn)
Tel: +(Telefoninumber)
<{E-mail}>

Norge

{Navn}
{Adresse}
N-0000 {poststed}
Tlf: + {Telefonnummer}
<{E-mail}>

Ελλάδα

{Όνομα}
 {Διεύθυνση}
 EL-000 00 {πόλη}
 Τηλ: + {Αριθμός τηλεφώνου}
 <{E-mail}>

España

{Nombre}
 {Dirección}
 ES-00000 {Ciudad}
 Tel: + {Teléfono}
 <{E-mail}>

France

{Nom}
 {Adresse}
 FR-00000 {Localité}
 Tél: + {Numéro de téléphone}
 <{E-mail}>

Hrvatska

{Ime}
 {Adresa}
 {Poštanski broj} {grad}
 Tel: + {Telefonski broj}
 <{e-mail}>

Ireland

{Name}
 {Address}
 {Town} {Postal code} -IE
 Tel: + {Telephone number}
 <{E-mail}>

Ísland

{Nafn}
 {Heimilisfang}
 IS-000 {Borg/Bær}
 Sími: + {Símanúmer}
 <{Netfang}>

Italia

{Nome}
 {Indirizzo}
 IT-00000 {Località}>
 Tel: + {Numero di telefono}
 <{E-mail}>

Κύπρος

{Όνομα}
 {Διεύθυνση}
 CY-000 00 {πόλη}
 Τηλ: + {Αριθμός τηλεφώνου}
 <{E-mail}>

Österreich

{Name}
 {Anschrift}
 A-00000 {Stadt}
 Tel: + {Telefonnummer}
 <{E-mail}>

Polska

{Nazwa/ Nazwisko:}
 {Adres:}
 PL – 00 000 {Miasto:}
 Tel.: + {Numer telefonu:}
 <{E-mail}>

Portugal

{Nome}
 {Morada}
 PT-0000–000 {Cidade}
 Tel: + {Número de telefone}
 <{E-mail}>

România

{Nume}
 {Adresă}
 {Oraș} {Cod poștal} – RO
 Tel: + {Număr de telefon}
 <{E-mail}>

Slovenija

{Ime}
 {Naslov}
 SI-0000 {Mesto}
 Tel: + {telefonska številka}
 <{E-mail}>

Slovenská republika

{Meno}
 {Adresa}
 SK-000 00 {Mesto}
 Tel: + {Telefónne číslo}
 <{E-mail}>

Suomi/Finland

{Nimi/Namn}
 {Osoite/Adress}
 FI-00000 {Postitoimipaikka/Stad}
 Puh/Tel: + {Puhelinnumero/Telefonnummer}
 <{E-mail}>

Sverige

{Namn}
 {Adress}
 SE-000 00 {Stad}
 Tel: + {Telefonnummer}
 <{E-mail}>

Latvija

{Nosaukums}

{Adrese}

{Pilsēta}, LV {Pasta indekss }

Tel: + {Telefona numurs}

<{E-mail}>

United Kingdom (Northern Ireland)

{Name}

{Address}

{Town} {Postal code} – UK

Tel: + {Telephone number}

<{E-mail}>

Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany