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: $10^{3.0}$ - $10^{4.5}$ EID_{50}.

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 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 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

Elanco GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5151

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}

PARTICULARS TO APPEAR ON THE 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: $10^{3.0}$ - $10^{4.5}$ EID_{50}*.
* EID_{50} = 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 lyophilisate

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]

[1]Of moderate intensity, seen on day 7 post vaccination. Lymphocyte repopulation occurs after day 7 post vaccination.
[2]Mild 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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

In drinking water use: One dose (min. $10^{3.0}$ EID_{50}) 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 1000 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 NUMBER AND PACK SIZES

Vm 52127/5151

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. 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
PV.XXI@elancoah.com

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

17. Other information

POM-V

Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 06 November 2025