SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Precise Lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live infectious bursal disease virus, strain LC 75: 10^3 - $10^{4,5}$ EID_{50} *
* EID_{50} = 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 hydrogen phosphate
Potassium dihydrogen phosphate
Lactose monohydrate
Skimmed milk powder

Appearance: 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.

Other precautions:

Not applicable.

3.6 Adverse events

Chickens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bursa of Fabricius lymphocyte depletion[1], Bursa of Fabricius degeneration[2]

[1]On day 7 post vaccination moderate generalised lymphocyte depletion is seen in the majority of birds.
[2]Lymphocyte repopulation occurs after day 7 post vaccination and by day 28 post vaccination only mild necrosis remains in some birds.

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.

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

One dose (min. 10^3 EID_{50}) should be administered per animal by drinking water 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 reconstituted vaccine should be protected from direct sunlight and temperatures above 25°C.

- 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. PHARMACOLOGICAL 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.

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 product 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 Europe Ltd.

7. MARKETING AUTHORISATION NUMBER

Vm 00879/5053

8. DATE OF FIRST AUTHORISATION

23 January 2003

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

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 11 February 2025