

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Precise
Lyophilisate for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose contains $10^{3.0}$ - $10^{4.5}$ EID₅₀ live IBD (Infectious Bursal Disease)-Virus, strain LC 75.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

1000 / 2500 / 5000 / 10 000 doses
10 x 1000 / 10 x 2500 / 10 x 5000 / 10 x 10 000 doses

5. TARGET SPECIES

Chickens (from 7 days old)

6. INDICATION(S)

For active immunisation of susceptible chickens against Infectious Bursal Disease (IBD/Gumboro).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from direct sunlight.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4187

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Precise
Lyophilisate for suspension

2. ACTIVE SUBSTANCE(S)

Live IBDV, LC 75

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 / 2500 / 5000 / 10 000 doses

4. ROUTE(S) OF ADMINISTRATION

In drinking water use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Directions for Use

AviPro® PRECISE
Lyophilisate for suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro® PRECISE

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:

1 dose contains min. 10^3 EID₅₀ and max $10^{4,5}$ EID₅₀ * live IBD (Infectious Bursal Disease)-Virus, strain LC 75.

Host system: embryonated SPF-hen's eggs.

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

Excipients:

Di-sodium hydrogen phosphate, Potassium di-hydrogen phosphate, Lactose monohydrate, Skimmed milk powder

4. INDICATION(S)

For active immunisation of susceptible chickens against Infectious Bursal Disease (IBD/Gumboro).

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

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.

6. ADVERSE REACTIONS

On day 7 post vaccination moderate to severe generalised lymphocyte depletion is seen in the majority of birds. Lymphocyte repopulation occurs after day 7 post vaccination and by day 28 post vaccination only mild necrosis remains in some birds. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon or pharmacist.

7. TARGET SPECIES

Chickens (from 7 days old)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One dose (min. 10^3 EID₅₀) should be administered per animal by drinking water from the age of 7 days onwards.

The determination of the vaccination date is dependant 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

Onset of immunity: 14 days

Duration of immunity demonstrated by challenge 28 days, antibodies may last up to 15 weeks.

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 day 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.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid stress before, during and after vaccination.

Protect the reconstituted vaccine from direct sunlight and temperatures of above 25°C.

Make sure that the drinking water and the drinkers are free of any trace of disinfectants and detergents to ensure the viability of the vaccine

Use the whole contents of the opened bottles at once.

Prepare the vaccine quantity only which can be applied within 2 hours.

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

The vaccine may spread to unvaccinated chickens, since it is excreted via the faeces for at least 9 days. Avoid spread to laying hens.

Overdosage is riskless, an insufficient vaccination, however, might lead to an inadequate immunisation.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Shelf life:

Store in a refrigerator (2 °C – 8 °C) Do not freeze. Protect from direct sunlight.

Do not use after the expiry date stated on the label.

Shelf life after reconstitution according to the instructions:

Reconstituted vaccine should be used within 2 hours

Prepare the vaccine quantity only which can be applied within 2 hours.

Protect the reconstituted vaccine from direct sunlight and temperatures of above 25°C.

12. SPECIAL WARNING(S)

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other.

Not to be used for birds in lay.

Do not mix with any substances other than water and skimmed milk. Ensure that the drinking water is cold, clean, and free from detergents and disinfectants to ensure the viability of the vaccine.

Operator warning: Wash and disinfect hands and equipment after vaccinating.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements and approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Registration no.: Vm 00879/4187

Legal category: POM-V

The following pack sizes are registered:

1000/2500/ 5000/ 10000 doses

10 x 1000/2500/ 5000/ 10000 doses

Approved 16 December 2020

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and includes a period at the end.