

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro® PRECISE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

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

Host system: embryonated SPF-eggs

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

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

Appearance: rose to red brown pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (from 7 days old)

4.2 Indications for use, specifying the target species

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

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

Onset of immunity: 14 days

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

4.3 Contraindications

Do not vaccinate unhealthy birds

4.4 Special warnings <for each target species>

None

4.5 Special precautions for use

i. Special precautions for use in animals

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

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

Ensure that the drinking water is cold, clean, and free from detergents and disinfectants to ensure the viability of the vaccine.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

On day 7 post vaccination moderate 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.

4.7 Use during lay

Not to be used for birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC Vet code: QI01AD09.

Pharmacotherapeutic group: Infectious bursal disease vaccine (Gumboro Disease)

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-sodium hydrogen phosphate,
Potassium di-hydrogen phosphate,

Lactose monohydrate,
Skimmed milk powder

6.2 Incompatibilities

Do not mix with any substances other than water and skimmed milk.
Ensure that the drinking water is cold, clean, non-chlorinated and free from detergents, disinfectants and metal ions.

6.3 Shelf life

36 months
Reconstituted vaccine should be used within 2 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:

- type I glass bottle
- chlorobutyl elastomer closure
- aluminium cap

The following pack sizes are registered:

1 x 1000/ 2500/ 5000/ 10000 doses
10 x 1000/ 2500/ 5000/ 10000 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4187

9. DATE OF FIRST AUTHORISATION

23 January 2003

10. DATE OF REVISION OF THE TEXT

December 2020

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 vertical line to the left of the name.