

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro GUMBORO VAC
Lyophilisate for suspension for chicken

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 dose contains min $10^{2.0}$ EID₅₀ and max $10^{3.7}$ EID₅₀* live IBD (Infectious Bursal Disease)-Virus, strain Cu-1M.

* EID₅₀ = 50% egg-infectious dose: the virus titre required to cause an infection in 50% of the inoculated embryos.
Host system: embryonated SPF-hen's eggs

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension
Appearance: Off-white pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

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

Onset of immunity: 3 weeks
Duration of immunity after 2nd vaccination: 14 weeks

4.3 Contraindications

Do not vaccinate unhealthy birds

4.4 Special warnings

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Vaccinated birds may excrete the vaccine strain via the faeces for at least 9 days following vaccination. During this time, the contact of immunodepressed and unvaccinated laying hens with vaccinated birds should be avoided.

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

To the user:

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

4.6 Adverse reactions (frequency and seriousness)

The vaccine may cause transient lymphocyte depletion in the Bursa of Fabricius. This does not result in an immune-suppressive effect.

4.7 Use during pregnancy, lactation or lay

AviPro GUMBORO VAC is designed for use in young birds (rearing/fattening period).

Do not use in birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

Studies have shown that ND- and IB-vaccines may be administered during the same time period as AviPro GUMBORO VAC.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

4.9 Amounts to be administered and administration route

One dose (min. 10^2 EID₅₀) should be administered per animal via the drinking water after resuspension.

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. In general the following recommendations for vaccination schedules can be made:

Vaccination is recommended twice in flocks where antibody levels vary widely between birds, or stock originates from different sources.

Broilers:

- with low/no levels of maternal antibodies: 7 days of age
- with high levels of maternal antibodies: 14 days of age

Layers/Breeders:

First vaccination at 3 - 4 weeks of age. Second vaccination is recommended 3 - 7 days later, in particular when there is a wide variation of antibody levels within the flock. Vaccination may also be carried out earlier, depending on the level of maternal antibody present and the infection pressure.

Application in the drinking water

- 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

No other signs than mentioned under 4.6 are seen after administration of ten times the maximum dose via the recommended routes.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC Vet code: QI01AD09.

Infectious bursal disease vaccine (Gumboro Disease)

The active ingredient of the vaccine is an attenuated Infectious Bursal Disease-virus strain Cu-1M of reliable immunogenicity which has lost its pathogenicity in serial passages in embryonated hens' eggs.

The strain is an intermediate one with an average score of bursal lesion of 0.4 (on a scale of 0 – 5) at 28 days post vaccination.

The vaccine stimulates active immunity against IBD-virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium hydrogen phosphate,
Potassium dihydrogen phosphate,
Lactose monohydrate,
Skimmed milk powder

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product than water or skimmed milk.

Ensure that the drinking water is cold, clean, non-chlorinated and free from detergents, disinfectants and metal ions.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months
Shelf-life after reconstitution according to directions: 2 hours

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C)

Do not freeze. Protect from direct sunlight

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

Do not freeze the reconstituted vaccine.

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:

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

The vaccine is available in the following pack sizes:

Bottle with 1000 doses

Bottle with 2500 doses

Bottle with 5000 doses

Bottle with 10000 doses

Transparent box packages:

Box with 10 x 1000 doses

Box with 10 x 2500 doses

Box with 10 x 5000 doses

Box with 10 x 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 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 00879/4192

9. DATE OF FIRST AUTHORISATION

18 November 1999

10. DATE OF REVISION OF THE TEXT

December 2020

Approved 16 December 2020

A handwritten signature in black ink, appearing to read "A. Hunter.", positioned below the approval date.