

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

TRANSPARENT BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro GUMBORO VAC
Lyophilisate for suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 dose contains min. $10^{2.0}$ 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

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

10 x 1000, 10 x 2500, 10 x 5000, 10 x 10 000 doses

5. TARGET SPECIES

For chickens

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered in the drinking water after resuspension.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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 see leaflet.

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

For animal treatment only - to be supplied only on veterinary prescription

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

Keep out of the reach and sight 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(S)

Vm 00879/4192

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

6R (10 ml) Glass vial type I

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro GUMBORO VAC
Lyophilisate for suspension
For chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

1000, 2500, 5000, 10 000 doses

4. ROUTE(S) OF ADMINISTRATION

To be administered in the drinking water after resuspension

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

AviPro GUMBORO VAC

Lyophilisate for suspension for chicken

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 GUMBORO VAC
Lyophilisate for suspension for chicken

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

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

Appearance: Off-white pellet

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

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

For administration via the drinking water after reconstitution.

One dose (min. $10^{2.0}$ EID₅₀) should be administered per animal via the drinking water.

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.

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.
- Only the volume of vaccine should be prepared which can be applied within 2 hours. 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

Avoid stress before, during and after vaccination.

Make sure that the drinking water and the drinkers are free of any trace of disinfectants and detergents.

Use the whole contents of the opened bottles at once.

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

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.

No other signs than mentioned under Section 6 are seen after administration of ten times the maximum dose via the recommended routes.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
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 dilution or reconstitution according to directions: 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. Do not freeze.

12. SPECIAL WARNING(S)

Live attenuated viral vaccine: do not spray or spill.
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.
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”.
Not to be used for birds in lay.

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 approved for use by the competent authorities.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

For animal treatment only.

Not all pack sizes may be marketed.

Reg. No: Vm 00879/4192

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 16 December 2020

A handwritten signature in black ink, consisting of a stylized initial followed by the name "Hunter." with a period.