

PARTICULARS TO APPEAR ON THE OUTER PACKAGE PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme
Lyophilisate for suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 dose contains $10^{1.5} - 10^{3.0}$ EID₅₀ live intermediate plus Infectious Bursal Disease virus, strain V217.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

500 / 1,000 / 2,500 / 5,000 / 10,000 doses
10 x 500 / 10 x 1,000 / 10 x 2,500 / 10 x 5,000 / 10 x 10,000 doses

5. TARGET SPECIES

Chickens (from 7 days old)

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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
Shelf life after reconstitution according to directions: 2 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from direct sunlight.
Protect the reconstituted vaccine from direct sunlight and temperatures of above 25 °C. Do not freeze.

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. To be supplied only on veterinary prescription.

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(S)

Vm 00879/4185

17. MANUFACTURER’S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme
Lyophilisate for suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose contains $10^{1.5}$ - $10^{3.0}$ EID₅₀ live intermediate plus Infectious Bursal Disease virus, strain V217.

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

500 / 1,000 / 2,500 / 5,000 / 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

Batch

7. EXPIRY DATE/

EXP
Shelf life after reconstitution according to directions: 2 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Elanco Europe Ltd.
Form 2, Bartley Way
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RG27 9XA
United Kingdom

PACKAGE LEAFLET FOR:
AviPro IBD Xtreme
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 IBD Xtreme
Lyophilisate for suspension

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

1 dose contains:

Active substance:

$10^{1.5}$ - $10^{3.0}$ EID₅₀* live intermediate plus IBD (Infectious Bursal Disease) virus, strain V217.

*EID₅₀ = 50 % embryo infective dose: the virus titre required to infect 50 % of the inoculated embryos

Host system: embryonated SPF-hen's eggs

Appearance: rose to red brown lyophilisate

4. INDICATION(S)

For active immunisation of chickens with maternally derived antibodies (breakthrough titre : 636) to reduce clinical disease, weight loss and acute lesions of the bursa of Fabricius associated with infection caused by very virulent Avian Infectious Bursal Disease (IBD) viruses.

ATC Vet code: QI01AD09

Onset of protection: 2 weeks.

Duration of immunity: 12 weeks based on serology

5. CONTRAINDICATIONS

Do not use in unhealthy birds.

6. ADVERSE REACTIONS

On day 7 post vaccination severe lymphocyte depletion is seen in the bursae of the majority of birds. Lymphocyte repopulation commences after day 7 post vaccination but by day 28 post vaccination notable lesions still remain in the bursae of the birds. The strain causes an average score of bursal lesion of 2.9 (out of 5 according to Ph Eur) at 21 days post vaccination.

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

7. TARGET SPECIES

Chickens (from 7 days old)

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

One dose should be administered per chicken in the drinking water after resuspension.

Vaccination programme

The determination of the vaccination date depends on a number of factors including status of maternal antibodies, type of bird, infection pressure, housing and management conditions.

In the case of a vv (very virulent)-IBD field challenge the field virus is extraordinarily virulent and requires the use of a vaccine able to break through relatively high levels of maternally derived antibodies (MDAs). AviPro IBD Xtreme can break through a maternal ELISA-antibody level of 636.

Homogenous levels of MDA levels facilitate a more accurate timing of the vaccination. To predict the age, when MDA have sufficiently decreased to allow effective vaccination it is advised, to test serum samples of at least 20 chicks by serology and apply the "Deventer Formula" for intermediate plus vaccines.

According to this formula the optimum age of vaccination is as follows:

1. Decide what percentage of the flock shall be representing and remove the highest titres that are excluded (e.g. 75 % of the flock; remove the highest 25 % of the titres).
2. Calculate the mean ELISA antibody titre of these birds.
3. Vaccination age = $\{(\log_2 \text{ titre bird } \% - \log_2 \text{ breakthrough}) \times t_{\frac{1}{2}}\} + \text{age at sampling} + \text{correction } 0-4$
(Bird % = ELISA titre of the bird representing a certain percentage of the flock
 $t_{\frac{1}{2}}$ = half-life time (ELISA) of the antibodies in the type of chickens being sampled
Age sampling = age of the birds at sampling
Correction 0-4 = extra days when the sampling was done at 0 to 4 days of age)

Birds should be at least 7 days of age at vaccination. The optimum age for vaccination may be calculated using the level of maternal antibody in the chicks at day old (Deventer formula), but normally lies in the range 12-21 days. Additional information on application and disease control is available from Lohmann Animal Health.

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

- Remove sealing cap and stopper from vaccine container.
- Suspend the vaccine in the corresponding amount of water and mix carefully.
- Prepare only the amount of vaccine that can be consumed within 2 hours.
- The vaccine is ready for use.

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.
- Use only cold and 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 at least 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.
- 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 1,000 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

Avoid stress before, during and after vaccination.

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.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

Protect the reconstituted vaccine from direct sunlight and temperatures of above 25 °C. Do not freeze.

12. SPECIAL WARNING(S)

Special warnings for each target species:

As described under 6.

Special precautions for use in animals:

The vaccine strain may spread to unvaccinated chickens, since it is excreted via the faeces for at least 9 days. Avoid spreading to laying hens, birds approaching lay and young birds below 7 days of age.

The vaccine should not be used in birds without maternally derived antibodies.

Spread of the vaccine strain to such birds should be prevented.

This vaccine induces serious and prolonged lesions in the bursa of Fabricius. It should therefore only be used to compete with very virulent (vv) IBD virus infection or to induce immunity in the face of still high maternally derived antibody (MDA) levels (breakthrough ELISA titre 636), where vaccines containing mild and intermediate strains have appeared to be insufficient.

MDA levels may differ throughout a given population. Therefore, depending on age and genetic factors of the birds IBD-like symptoms or mortality may occur in animals with low MDA level or without MDAs.

Whenever the field situation allows this, try to switch back from an intermediate plus vaccine to an intermediate.

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

Wash and disinfect hands and equipment after vaccinating.

Lay:

Do not use in birds in lay or close to the onset of lay.

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.

Overdose (symptoms, emergency procedures, antidotes):

No other signs have been observed as described under 6. following administration of a ten-fold dose.

Incompatibilities:

Do not mix with any other substances than water or skimmed milk.

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

Medicines should not be disposed of via wastewater or household waste. 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.

MA-No: Vm 00879/4185

The vaccine is available in the following pack sizes:

Box containing 1 or 10 vials with 500 / 1,000 / 2,500 / 5,000 / 10,000 doses per vial.

Not all pack sizes may be marketed.

Approved 16 December 2020

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