SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme
Lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live intermediate plus infectious bursal disease virus, strain V217: $10^{1.5}$ - $10^{3.0}$ EID_{50}*.
*EID_{50} = 50 % embryo infective dose: the virus titre required to infect 50 % of the inoculated embryos

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate dihydrate
Lactose monohydrate
Potassium dihydrogen phosphate
Skim milk powder

Appearance: rose to red brown lyophilisate

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For active immunisation of chickens from 7 days of age 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.

Onset of immunity: 2 weeks
Duration of immunity: 12 weeks after vaccination based on serology

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The vaccine strain can spread to unvaccinated chickens, since it is excreted via the faeces for at least 9 days. Special precautions should be taken to avoid spreading of the vaccine strain 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after vaccinating.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion[1]

[1]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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 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.

3.9 Administration routes and dosage

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.
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 = {($\log_2$ titre bird % - $\log_2$ breakthrough) x t_} + age at sampling + correction 0-4
   (Bird % = ELISA titre of the bird representing a certain percentage of the flock
   t_ = 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 Elanco 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other signs have been observed as described under 3.6 following administration of a ten-fold dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD09

The active ingredient of the lyophilisate is a live intermediate plus infectious bursal disease virus strain V217 which stimulates active immunity against IBD virus.

The strain causes an average score of bursal lesion of 2.9 (out of 5 according to Ph Eur) at 21 days post vaccination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months
Shelf life after reconstitution according to directions: 2 hours

5.3 Special precautions for storage

Store and transport refrigerated (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.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:
- type I glass vial
- type I rubber closure

The vaccine is available in the following packaging sizes:
Cardboard box containing 1 or 10 glass vials with 500 / 1,000 / 2,500 / 5,000 / 10,000 doses per vial.

Not all pack sizes may be marketed.

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

(Alternative for UK(NI) only: Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.)

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBER

Vm 00879/3032

8. DATE OF FIRST AUTHORISATION

29 May 2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 15 December 2023