SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme
Lyophilisate for suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 dose contains $10^{1.5}$ - $10^{3.0}$ EID_{50}* live intermediate plus IBD (Infectious Bursal Disease) virus, strain V217.
*EID_{50} = 50 % embryo infective dose: the virus titre required to infect 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: rose to red brown lyophilisate

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 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.

Onset of protection: 2 weeks.
Duration of immunity: 12 weeks based on serology

4.3 Contraindications

Do not use in unhealthy birds.

4.4 Special warnings for each target species

As described under 4.6.

4.5 Special precautions for use

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.

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

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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 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.

<u>Drinking water application:</u>

- 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.

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

No other signs have been observed as described under 4.6 following administration of a ten-fold dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: avian infectious bursal disease virus (Gumboro disease), 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dihydrate
Lactose monohydrate
Potassium dihydrogen phosphate
Skim milk powder

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 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 from direct sunlight and temperatures of above 25 °C. Do not freeze.

6.5 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:
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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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 00879/4185

9. DATE OF FIRST AUTHORISATION

29 May 2008

10. DATE OF REVISION OF THE TEXT

December 2020

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