

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme
Lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains live intermediate plus infectious bursal disease virus, strain V217: $10^{1.5}$ - $10^{3.0}$ EID₅₀.

3. 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

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/3032

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro IBD Xtreme

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 / 1,000 / 2,500 / 5,000 / 10,000 doses live IBDV, V217

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro IBD Xtreme
Lyophilisate for use in drinking water for chickens

2. Composition

Each dose contains:

Active substance:

Live intermediate plus IBD (infectious bursal disease) virus, strain V217: $10^{1.5} - 10^{3.0}$ EID₅₀*.

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

Appearance: rose to red brown lyophilisate

3. Target species

Chickens

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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.

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.

Laying birds:

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

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:

No other signs have been observed as described under 7. following administration of a ten-fold dose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):

Bursa of Fabricius lymphocyte depletion ¹
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¹On 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes 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 = $\{(\log_2 \text{ titre bird } \% - \log_2 \text{ breakthrough}) \times t_{\frac{1}{2}}\} + \text{age at sampling}$

+ 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 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

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 periods

Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA-No : Vm 00879/3032

The vaccine is available in the following pack 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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien

{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de
téléphone/Telefoonnummer/
Telefonnummer}
<{E-mail}>

Lietuva

{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Република България

{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Luxembourg/Luxemburg

{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de
téléphone/Telefonnummer}
<{E-mail}>

Česká republika

{Název}
<{Adresa}
CZ {město}>
Tel: + {telefonní číslo}
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Magyarország

{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Danmark

{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Malta

{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Deutschland

{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
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Nederland

{Naam}
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Tel: + {Telefoonnummer}
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France

{Nom}
<{Adresse}>
FR-00000 {Localité}>
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<{E-mail}>

Hrvatska

{Ime}
<{Adresa}>
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Tel: + {Telefonski broj}
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Ireland

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<{Address}>
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
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Sími: + {Símanúmer}
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Norge

{Navn}
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N-0000 {poststed}>
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Österreich

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Tel: + {Telefonnummer}
<{E-mail}>

Latvija

{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

United Kingdom (Northern Ireland)

{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>>

Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany



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