

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**CARDBOARD BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AviPro THYMOVAC  
Lyophilisate for use in drinking water.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 dose contains live chicken anaemia virus (CAV), strain Cux-1:  $10^{4.5} - 10^{5.5}$  TCID<sub>50</sub>

**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. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

**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). Protect from direct sunlight. Do not freeze.

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 00879/5042

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V

Veterinary medicinal product subject to prescription.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS**  
**GLASS VIAL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AviPro THYMOVAC

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

500/ 1,000/ 2,500/ 5,000/ 10,000 doses live CAV, Cux-1

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after reconstitution according to directions: 2 hours

**5. ROUTE(S) OF ADMINISTRATION**

For oral administration in drinking water.

**6. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AviPro THYMOVAC  
Lyophilisate for use in drinking water.

### **2. COMPOSITION**

Each dose contains:

#### **Active substance:**

Live chicken anaemia virus (CAV), strain Cux-1:  $10^{4.5} - 10^{5.5}$  TCID<sub>50</sub>\*  
\*TCID<sub>50</sub> = tissue culture-infectious dose 50 %: the virus titre required to cause infection in 50 % of the inoculated cell cultures.

Appearance: red to brown lyophilisate.

### **3. TARGET SPECIES**

Chickens

### **4. INDICATIONS FOR USE**

For protection of the vaccinated breeders from 8 weeks of age against excretion of the chicken anaemia virus and transmission of the virus to eggs.

For this active immunisation:

Onset of immunity: 4 weeks after vaccination

Duration of immunity: 43 weeks after vaccination demonstrated by challenge.

For passive protection conferred to the progeny against clinical signs and lesions of chicken anaemia. The protection of the progeny is guaranteed for up to 51 weeks after vaccination of the breeder, and chicks are protected at one day old (as demonstrated by challenge).

### **5. CONTRAINDICATIONS**

None

### **6. SPECIAL WARNINGS**

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Vaccination should be performed from 8 weeks of age onwards, but no later than 6 weeks before the onset of lay in order to ensure that protective immunity has developed prior to the onset of lay.

The vaccine strain can spread to unvaccinated chickens, since vaccinated chickens may excrete the vaccine strain via the faeces for at least 14 days following vaccination. Since the virus may cause clinical symptoms in very young chicks, a transfer to unprotected birds must be avoided. Special precautions should be taken to avoid spreading of the vaccine strain to laying hens, birds approaching lay and young birds below 3 weeks of age". The vaccine should not be used in multi-age sites.

Avoid stress before, during and after vaccination.

The vaccine virus can be found in different organs and tissues between day 7 and day 49 after vaccination.

To reduce infection pressure before onset of immunity, the litter should be removed and the poultry house should be cleaned between the raising passages.

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

The vaccine contains live virus, therefore, personal protective equipment consisting of gloves, glasses or goggles should be worn when handling the veterinary medicinal product to avoid any contamination, e.g. by sprinkling or spilling.

Care should also be taken in handling poultry faeces as vaccine virus may be excreted via the faeces for at least 14 days.

Wash and disinfect hands and equipment after use.

Laying birds:

Do not use in birds in lay and no later than six weeks before 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 decided on a case by case basis.

Overdose :

No adverse reactions were observed following administration of a 10-fold overdose.

Major incompatibilities:

Do not mix with any other medicinal product.

## **7. ADVERSE EVENTS**

Chickens:

None known.

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.

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

For administration via the drinking water after reconstitution.  
One dose should be administered to each bird.

Vaccinate from 8 weeks of age, at least 6 weeks before onset of lay.

Dosage and 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 the drinking water and 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.
- Birds should be given a single vaccination of one dose.

- Ideally vaccine should be administered in the volume of water consumed by the birds in up to 2 hours. Apply diluted vaccine to cold and fresh water at a rate of 1,000 doses of vaccine to maximally 40 litres of water for 1,000 chickens. 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.

Carefully follow the instructions for correct administration in order that all birds receive the correct dose. Insufficient vaccination may lead to reduced efficacy.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Do not use in birds in lay and no later than six weeks before the onset of lay.

## **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). Protect from direct sunlight. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5042

### Nature of primary packaging elements:

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 or 10,000 doses per vial.

Not all pack sizes may be marketed.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 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

Tel: +44 3308221732

[PV.GBR@elancoah.com](mailto:PV.GBR@elancoah.com)

### Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven

## 17. OTHER INFORMATION

POM-V

For animal treatment only.

Vaccination of breeding flocks induces immunity against infections caused by chicken anaemia virus. This prevents excretion of the virus, preventing vertical spread to eggs and horizontal spread via the faeces. Breeders are vaccinated at an age at which chicken anaemia virus does not cause clinical symptoms any longer, the aim of vaccination is to transfer maternal antibodies to the progeny in order to protect the progeny from infection in the period between hatching and development of their own resistance to chicken infectious anaemia.

*Gavin Hall*  
Approved: 17 December 2024