

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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: $10^{4.5} - 10^{5.5}$ TCID₅₀
Host system: embryonated SPF-hen's eggs

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.

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 (breeders from 8 weeks of age)

6. INDICATION(S)

For the active immunisation of breeder chickens and passive immunisation of their progeny against chicken infectious anaemia.

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

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)

UK only

Vm: 00879/4191

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To be supplied only
on
veterinary
prescription

IE only

VPA: 10977/009/001

POM

17.MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro THYMOVAC
Lyophilisate for use in drinking water.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose contains live Chicken Anaemia Virus (CAV), strain Cux-1: $10^{4.5}$ - $10^{5.5}$ TCID₅₀

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

For oral administration in drinking water.

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
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
AviPro THYMOVAC
Lyophilisate for use in drinking water

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 THYMOVAC
Lyophilisate for use in drinking water.

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

1 dose contains

Active substance:

Live Chicken Anaemia Virus (CAV), strain Cux-1: $10^{4.5} - 10^{5.5}$ TCID₅₀*

*TCID₅₀ = tissue culture-infectious dose 50 %: the virus titre required to cause infection in 50 % of the inoculated cell cultures.

Host system: embryonated SPF-hen's eggs.

Appearance: red to brown lyophilized cake.

4. INDICATION(S)

For protection of the vaccinated breeder against excretion of the chicken anaemia virus and transmission of the virus to eggs.

For this active immunisation,

onset of immunity: 4 weeks

duration of immunity: 43 weeks 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).

ATC Vet code: QI01AD04.

5. CONTRAINDICATIONS

Do not use in unhealthy birds.

6. ADVERSE REACTIONS

None.

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

7. TARGET SPECIES

Chickens (breeders from 8 weeks of age).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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. Avoid stress before, during and after vaccination. Use the whole contents of the opened bottles at once.

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). 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 WARNING(S)

Special precautions for use in animals:

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 virus may spread to unvaccinated chickens, since it is excreted via the faeces for at least 14 days. Since the virus may cause clinical symptoms in very young chicks, a transfer to unprotected birds must be avoided. Avoid spreading to laying hens, birds approaching lay and young birds below 3 weeks of age". The vaccine should not be used in multi-age sites.

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 care should be taken (e.g. by wearing gloves, protecting eyes, washing and disinfecting hands, etc.) 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.

Lay:

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 (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

Do not mix with any other medicinal product.

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

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.

UK only

Vm: 00879/4191

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To be supplied only
on veterinary
prescription

IE only

VPA: 10977/009/001

POM

Prescription Only
Medicine

Nature of primary packaging elements:

The vaccine is available in the following packaging sizes:

Box containing 1 or 10 type 1 glass bottles with 500, 1,000, 2,500, 5,000 or 10,000 doses per bottle. These bottles have a chlorobutyl elastomer closure and are sealed with a tear off-aluminium cap

Not all pack sizes may be marketed.

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.

Approved 16 December 2020

