SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro THYMOVAC
Lyophilisate for use in drinking water.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live chicken anaemia virus (CAV), strain Cux-1: $10^{4.5}$ - $10^{5.5}$ $TCID_{50}$*

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.
Appearance: red to brown lyophilisate

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

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).

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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 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.

Special precautions for the protection of the environment
Not applicable

Other precautions
Not applicable

4.6 Adverse reactions (frequency and seriousness)

Chickens:
None known.

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 also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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

4.9 Amount(s) to be administered and administration route

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

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 20 – 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.

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Chicken Anaemia Virus.

ATCvet code: QI01AD04.

The veterinary medicinal product is intended to stimulate active immunity in breeder chickens and to transfer passive immunity to the progeny.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium dihydrogen phosphate,
Disodium phosphate dihydrate,
Lactosemonohydrate,
Skimmed milk.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:
The vaccine is available in the following packaging sizes:
Cardboard box containing 1 or 10 type 1 glass vials with 500, 1,000, 2,500, 5,000 or 10,000 doses per vial. These vials have a type I rubber closure and are sealed with a tear off-aluminium cap.

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

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.

7. MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5071

9. DATE OF FIRST AUTHORISATION

28 April 2009

10. DATE OF REVISION OF THE TEXT

March 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 18 March 2025

Gavin Hall