Issued: June 2023
AN: 02415/2021

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE
Suspension for use in drinking water for chicken

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose contains:

Active substance:
Avian Encephalomyelitis virus, live, strain 1143 Calnek $10^{3.0}$ - $10^{4.5}$ EID_{50}*
Host system: embryonated SPF chickens' eggs

*EID_{50} = 50 % embryo infective dose: the viral titre required to induce an infection in 50 % of embryos inoculated with the virus.

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

3. PHARMACEUTICAL FORM

Suspension for use in drinking water
Appearance: yellow-brown, cloudy liquid

4. CLINICAL PARTICULARS

4.1 Target species

Chicken

4.2 Indications for use, specifying the target species

For active immuni**s**ation of future layers and breeding chickens from 14 weeks of age against Avian Encephalomyelitis Virus, to induce passive immunity in young chickens against infection with Avian Encephalomyelitis.

Onset of immunity: 10 weeks demonstrated by challenge of progeny.

Duration of immunity: 39 weeks demonstrated by challenge of progeny

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Eggs of vaccinated breeding birds may be used for breeding purposes not earlier than 4 weeks after vaccination.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine virus is able to spread horizontally from vaccinated to non-vaccinated chickens. AE virus can naturally infect partridges, turkeys, pheasants, and pigeons. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to non-vaccinated chickens, partridges, turkeys, pheasants, pigeons, and other susceptible species. All animals in the population must be vaccinated at the same time. To avoid additional stress for the vaccinated animals, no other immunisattion should be performed for two weeks before and after the AE vaccination.

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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

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

For administration via drinking water.
One vaccine dose per animal aged 14 weeks and older.
All animals of the population must be vaccinated.

The vaccine should be dissolved in the amount of drinking water consumed by the animals
within 2 hours. The vaccine must be administered to the drinkers immediately after dissolution so that it is consumed by the animals within 2 hours at most after dilution.

To ensure the vaccine is consumed quickly, drinking water should be withheld from the animals for 1 -2 hours prior to vaccination. It must be ensured that all animals have adequate access to the vaccine suspension, but not have access to normal drinking water until the vaccine has been consumed.

Method of administration

Administration via drinking water

- Determine the required number of vaccine doses and the quantity of water (see below).
- Use the total contents of the vaccine bottles per one chicken house or drinker systems.
- All equipment used for vaccination (lines, hoses, drinkers etc.) should be thoroughly cleaned and must be free from residues of cleaning agents and disinfectants.
- Use only cool, clean, and fresh water, preferably free of chlorine and metal ions. Skimmed milk powder (2 - 4 g/litre water) or skimmed milk (20 - 40 ml/litre water) can improve the quality of the drinking water and prolong the activity of the vaccine; however, this supplement should be added to the water 10 minutes **before** adding the vaccine.
- Open the vaccine bottle under water and dilute its contents. Ensure that any remaining vaccine is completely emptied by rinsing the bottle and rubber stopper with water.
- Lines filled with water must be emptied before administering the vaccine suspension.

Add the diluted vaccine suspension to cold, fresh water such that, as a rule of thumb, 1,000 vaccine doses are dissolved in one litre of water per age in days for 1,000 chickens, e. g. 10 litres would be required for 1,000 chickens aged 10 days old.

Under hot climatic conditions and for heavy breeds, this amount may be increased to a maximum of 40 litres per 1,000 animals. In case of doubt, the daily water consumption should be determined before vaccination.

To reduce the risk of infection before the onset of immunity, the litter should be removed, and the chicken house cleaned between treatment cycles in the breeding unit.

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

No adverse reactions have been observed after 10-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live virus vaccines for poultry, Avian Encephalomyelitis Virus
ATCvet code: QI01AD02

The vaccine contains the enterotropic virus strain 1143 Calnek which is not adapted to eggs. The parent animals are vaccinated at a time, in which they are usually age-resistant to the disease. The purpose of the vaccination is the development of neutralising maternal antibodies that are transmitted via the yolk sack to the chicks to protect them against infection during the first few weeks of life.
Results from animal studies demonstrate that specific antibodies against Avian Encephalomyelitis Virus are detected from 3 weeks post vaccination. Field data demonstrate that specific antibodies are present in vaccinated animals for 44 weeks after vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium hydrogen phosphate
Lactose monohydrate
Potassium dihydrogen phosphate
Skim milk powder
Water for injections

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: 1 year
Shelf life after dilution according to directions: 2 hours

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from direct sunlight.

Shelf life after dilution according to directions:
Protect finished vaccine suspension against direct sunlight and temperature above 25°C as well as frost!

6.5 Nature and composition of immediate packaging

Glass bottle Type I (Ph. Eur.) with beaded rim with chlorobutyl elastomer closure.
The bottles are sealed with aluminium tear-off caps.

The vaccine is available in the following pack sizes:
Pack with 1,000 vaccine doses
Pack with 2,500 vaccine doses
Pack with 5,000 vaccine doses
Pack with 10,000 vaccine doses

Bundle packaging:
Pack with 10 x 1,000 vaccine doses
Pack with 10 x 2,500 vaccine doses
Pack with 10 x 5,000 vaccine doses
Pack with 10 x 10,000 vaccine doses
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 00879/5005

9. DATE OF FIRST AUTHORISATION

21 June 2023

10. DATE OF REVISION OF THE TEXT

June 2023

Approved: 21 June 2023