ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE Suspension for use in drinking water for chicken

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose contains Avian Encephalomyelitis virus, live, strain 1143 Calnek, $10^{3.0}$ – $10^{4.5}$ EID_{50}
Host system: embryonated SPF chickens' eggs

3. PHARMACEUTICAL FORM

Suspension for use in drinking water

4. PACKAGE SIZE

Pack with 1,000 vaccine doses
Pack with 2,500 vaccine doses
Pack with 5,000 vaccine doses
Pack with 10,000 vaccine doses

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

5. TARGET SPECIES

Chicken

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once diluted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from frost.
Protect from direct sunlight.

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. To be supplied only on veterinary prescription.

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

Vm 00879/5005

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

AE virus, live, strain 1143 Calnek

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses
2,500 doses
5,000 doses
10,000 doses

4. ROUTE(S) OF ADMINISTRATION

For use in drinking water.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once diluted use within 2 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

AviPro AE

Suspension for use in drinking water for chicken

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
27472 Cuxhaven
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro AE Suspension for use in drinking water for chicken

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

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

Appearance: yellow-brown, cloudy liquid

4. INDICATION

For active immunisation 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chicken

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

The vaccination should not be later than 4 weeks before the start of breeding in order to avoid the transmission of the vaccine virus to the offspring.
Use the entire contents of the opened container at once.
All animals of the population must be vaccinated.

10. WITHDRAWAL PERIOD

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 frost.
Protect from direct sunlight.

Shelf life after dilution according to directions:
Only the amount of vaccine may be prepared that can be consumed by the animals within 2 hours. Protect finished vaccine suspension against direct sunlight and temperature above 25°C as well as frost!
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

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.

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 immunizations 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.

Lay:
Laying and breeding 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 (symptoms, emergency procedures, antidotes):
No adverse reactions have been observed after 10-fold overdose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste.
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

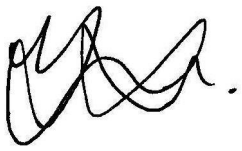
15. OTHER INFORMATION

IMMUNOLOGICAL PROPERTIES
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.

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.



Approved: 21 June 2023