

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

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

AviPro Salmonella Vac E

Lyophilisate for use in drinking water

**2. STATEMENT OF ACTIVE SUBSTANCES**

One dose contains:

*Salmonella enterica*, subsp. *enterica*, serovar Enteritidis, strain Sm24/Rif12/Ssq,  
Live 1 x 10<sup>8</sup> CFU to 6 x 10<sup>8</sup> CFU

**3. PACKAGE SIZE**

1 x 500, 1,000, 1,500, 2,000, 2,500, 3,000, 3,500, 4,000, 4500, and 5,000 doses.

10 x 500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, and 5000 doses.

**4. TARGET SPECIES**

Chickens.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

For oral use after resuspension in drinking water.

**7. WITHDRAWAL PERIODS**

Withdrawal periods: Meat and offal 21 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator.

Do not freeze.

Protect from light.

**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 NUMBER**

Vm 00879/4189

**15. BATCH NUMBER**

Lot {number}

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

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

AviPro Salmonella Vac E

Lyophilisate for use in drinking water

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

*Salmonella* Enteritidis, strain Sm24/Rif12/Ssq, Live.

500 doses  
1,000 doses  
1,500 doses  
2,000 doses  
2,500 doses  
3,000 doses  
3,500 doses  
4,000 doses  
4,500 doses  
5,000 doses

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

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

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

AviPro Salmonella Vac E

Lyophilisate for use in drinking water

**2. Composition**

One dose contains:

**Active substances:**

Salmonella enterica, subsp. enterica, serovar Enteritidis, strain Sm24/Rif12/Ssq,  
Live min. 1 x 10<sup>8</sup> CFU\* and max 6 x 10<sup>8</sup> CFU\*

\*CFU – colony forming units.

White to greyish/ brownish lyophilised cake.

**3. Target species**

Chickens

**4. Indications for use**

For active immunisation of healthy susceptible, immune competent chickens to reduce mortality, colonisation, invasion and faecal excretion due to *Salmonella* Enteritidis, phage type 4.

Onset of immunity: 15 days.

Duration of immunity: 6 to 8 weeks following a single dose and 60 weeks following the 3 dose programme.

**5. Contraindications**

None.

**6. Special warnings**

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

The vaccine strain is highly sensitive to quinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol, doxycycline, detergents and environmental noxae.

Vaccinated birds may excrete the vaccine strain for up to 16 days following vaccination. The vaccine strain can spread to susceptible birds in contact with vaccinated chickens.

The differentiation between vaccine and field strains is done by means of an antibiogram. In contrast to field strains, vaccine strains are sensitive to erythromycin (recommended concentration 15-30 µg/ml) and resistant to streptomycin and rifampicin (recommended concentration 200 µg/ml).

The presence of maternal antibodies to *Salmonella* Enteritidis may reduce the effect of vaccination over the first 4 days of life.

The vaccine strain can also be distinguished from field strains by molecular biology methods, such as a real-time polymerase chain reaction (PCR) method. For detailed information, please contact the marketing authorization holder.

Depending on the test system used, oral vaccination may result in low seropositive reactions of individual birds in a flock. Since serological *Salmonella* monitoring is a flock test only, positive findings have to be confirmed, e.g. by bacteriology.

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

Use gloves when reconstituting the vaccine. Open vial under water to avoid aerosols. Disinfect and wash hands after handling the vaccine. Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician. The vaccine strain is sensitive to a number of antibiotics including quinolones (ciprofloxacin).

Care should be taken to wash and disinfect hands after handling poultry faeces, particularly in the first 7 days after vaccination of birds.

Immunocompromised persons are advised to avoid contact with the vaccine and recently vaccinated animal.

Laying birds:

Do not use in birds in lay and within 3 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

Antibacterials shall not be administered 3 days before and after immunization.

If antibiotic treatment is inevitable, the respective animals must be re-immunized, however, not earlier than three days after this treatment.

Day old chicks may be vaccinated with the vaccine by the oral route.

The vaccine may be administered on the same day as AviPro *Salmonella* Vac T, but not simultaneously.

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:

There were no undesired effects after application of the 10-fold dose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

**7. Adverse events**

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 at:

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

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

## **8. Dosage for each species, routes and method of administration**

### Dosage and use:

One dose should be administered per animal.

The vaccine may be used from the 1st day of life.

### Recommended vaccination scheme:

Broiler: For birds up to 6 weeks of age, a single dose from one day of age.

Layers and Breeders: A single dose from one day of age followed by a second vaccination at 6 to 8 weeks of age and a third vaccination at 16-18 weeks at least 3 weeks before onset of lay.

## **9. Advice on correct administration**

### **Drinking water:**

1. Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap etc.
2. Open the vaccine ampoule under water and dissolve thoroughly. As the concentrated vaccine is slightly viscous, care should be taken to empty the ampoule completely by rinsing it in water.
3. Then thoroughly dissolve in a 1 litre jug and stir well before mixing with more water in a 10 litre bucket before application. The vaccine must be stirred thoroughly for several minutes at each stage. Do not split large vials to vaccinate more than 1 house or drinking system, as this leads to mixing errors.
4. As a guide, apply the diluted vaccine to cold and fresh water at the rate of 1 liter of water per 1,000 birds per day of age e.g. 10 litres would be needed for 1,000 10-day old chickens. Use water meter recordings for the previous day to accurately determine the correct quantity of water in each case. Low-fat skimmed milk powder (i.e. <1 % fat) should be added to the water (2-4 g per liter) or skimmed milk (20 - 40 ml per litre of water) to increase the stability of the vaccine. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.

5. Allow water in the drinkers to be consumed so that levels prior to vaccine applications are minimal. If water is still present the lines must be drained before applying the vaccine. The vaccine treated water should be used within 4 hours. It should be ensured that all birds drink during this period. Birds drinking behavior varies. It may be necessary to withhold drinking water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period. The aim is to give every bird one dose of vaccine. A period of thirst of up to 2-3 hours before vaccination may be necessary to achieve this.

#### **10. Withdrawal periods**

Meat and offal: 21 days.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.  
Store in a refrigerator (2°C – 8°C).  
Do not freeze.  
Protect from light.

Shelf life after reconstitution according to directions: 4 hours  
Do not use this veterinary medicinal product after the expiry date which is stated on the label.  
The expiry date refers to the last day of that month.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

#### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

#### **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 00879/4189

1 x 500/1,000/1,500/2,000/2,500/3,000/3,500/4,000/4,500/5,000 doses  
10 x 500/1,000/1,500/2,000/2,500/3,000/3,500/4,000/4,500/5,000 doses

Not all pack sizes may be marketed.

**15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' 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
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*Gavin Hall*

Approved: 24 September 2025