SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella vac E
Lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substances:

Salmonella enterica, subsp. enterica, serovar Enteritidis, strain Sm24/Rif12/Ssq, Live min.1 x 10^8 CFU* and max. 6 x 10^8 CFU*
*CFU – colony forming units.

Excipients:

Qualitative composition of excipients and other constituents
Soy peptone
Sucrose
Gelatin
HEPES-buffer

White to greyish/ brownish lyophilised cake.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.

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

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 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.

3.6 Adverse events

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.
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.

3.9 Administration routes and dosage

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 onsetof lay.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 21 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AE01

To stimulate active immunity to *Salmonella* Enteritidis, phage type 4.
The vaccine strain is a natural metabolic drift mutant, that lacks or does not express certain metabolic pathways, which results in attenuation.
The genetic basis results in defective ribosomal protein S12 affecting polypeptide synthesis (streptomycin resistance) and defective RNA polymerase affecting transcription of DNA to RNA (rifampicin resistance).
The vaccine strain also has attenuations that increase the permeability of the cell membrane to noxae such as detergents and antibiotics. This means the strain has poor survival in the environment and is highly sensitive to fluoroquinolones and unlike field strains is sensitive to erythromycin.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after reconstitution according to directions: 4 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from light

5.4 Nature and composition of immediate packaging

Vials made of type I pharmaceutical glass.
The vials are closed with type I rubber closures with aluminium tear-off crimp caps.

The following pack sizes are registered:
1 x 500,1000,1500,2000,2500,3000,3500,4000,4500, and 5000 doses.

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

Not all pack sizes may be marketed.

5.5 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 or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 00879/5057

8. DATE OF FIRST AUTHORISATION

11 December 2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 06 November 2025