SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro® SALMONELLA VAC E

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose contains:

$1 \times 10^8 - 6 \times 10^8$
CFU attenuated *Salmonella* Enteritidis bacteria, strain Sm24/RifI2/Ssq

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Freeze-dried live vaccine for reconstitution in drinking water for oral application.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the 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.
Immunity develops within 14 days of vaccination and remains for 6 to 8 weeks following a single dose and for 60 weeks following the 3 dose programme.

4.3 Contraindications

Do not vaccinate sick birds. Do not vaccinate birds in lay. Vaccination of birds intended as laying birds must be completed 3 weeks before point of lay.

4.4 Special warnings <for each target species>

The vaccine strain may spread to susceptible birds in contact with vaccinates. Studies have shown that vaccinated birds shed the vaccine strain for up to 16 days.

4.5 Special precautions for use

i. Special precautions for use in animals

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

The differentiation between vaccine and field strains is done by means of an antibiogramme. 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.

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.

ii. 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. If the vaccine has been swallowed seek medical advice. 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.

Operators should not handle vaccine if known to be suffering from immunosuppressive disease.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The vaccination of birds intended as layers should be completed 3 weeks before point of lay.

4.8 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.
Day old chicks may be vaccinated with AviPro SALMONELLA VAC E by the oral route and Marek's vaccine (both turkey herpes and Rispens) by injection.

AviPro SALMONELLA VAC E may be administered on the same day as AviPro SALMONELLA VAC T, but not simultaneously.

4.9 Amounts to be administered and administration route

Dosage and use:
One dose should be administered per animal.
The vaccine may be used as from the 1st day of life.

Recommended vaccination scheme:

DOSAGE REGIMEN

Broiler:	For birds up to 6 weeks of age, a single dose at 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 point of 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 and its top completely by rinsing them 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. 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 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 grams 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.

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

After application of the 10-fold dose there were no side-effects.

4.11 Withdrawal period(s)

21 days.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01AE01

To stimulate active immunity to *Salmonella* Enteritidis, phage type 4.
The vaccine strain is a natural metabolic drift mutant, i.e. it lacks or does not express certain metabolic pathways which result 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soy peptone, sucrose, gelatin, HEPES-buffer.

6.2 Incompatibilities

Do not mix with any other immunological products.

6.3 Shelf life

The shelf life of the lyophilized vaccine is 24 months, after dissolution 4 hours.

6.4 Special precautions for storage

Store at +2 °C to +8 °C.
Do not freeze. Protect from sunlight

6.5 Nature and composition of immediate packaging

EP Type I glass vials
They are closed with EP Type I stoppers of chlorbutyl rubber and sealed with aluminium caps.

Vials of 500,1000,1500,2000,2500,3000,3500,4000,4500, and 5000 doses.

Packs of 10 by 500,1000,1500,2000,2500,3000,3500,4000,4500, and 5000 doses.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Destroy the unused live vaccine or reconstituted vaccine with disinfectant before disposal.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
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United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4189

9. DATE OF FIRST AUTHORISATION

11 December 2000

10. DATE OF REVISION OF THE TEXT

December 2020

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