SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Vac T

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose contains:

Active substance:
At least 1 x 10^8 to 6 x 10^8 CFU* live attenuated *Salmonella* Typhimurium bacteria,
strain Nal 2/Rif 9/Rtt

*CFU = Colony Forming Units

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

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.
Appearance: White to gray-brown pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (future breeders and layers, broilers) from one day old.

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce mortality, colonisation, shedding and faecal excretion of *Salmonella* Typhimurium.
Immunity develops within 15 days of first vaccination.
Following the three dose programme immunity remains for 50 weeks, in layers and breeders, and for at least 6 weeks after one vaccination in broilers.

4.3 Contraindications

Do not use in sick birds. Do not use in birds in lay and within 3 weeks before onset of lay.

4.4 Special warnings for each target species

The vaccine may spread to susceptible birds in contact with vaccinates.

4.5 Special precautions for use

i. Special precautions for use in animals

The vaccine strain is sensitive to fluoroquinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol, doxycycline, detergents and environmental noxae.
Vaccinate healthy birds only.
The differentiation between vaccine and field strains is made by means of an antibio-gramme. In contrast to field strains, vaccine strains are sensitive to erythromycin (re-commended concentration 15 – 30 µg/ml) and resistant to nalidixic acid (recommended concentration 20 µg/ml) and rifampicin (recommended concentration 200 µg/ml).
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 must be confirmed, e.g. by bacteriology.

Vaccinated birds may excrete the vaccine strain up to 14 days following vaccination.

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

Use gloves when reconstituting vaccine. Open vial under water to avoid aerosols. Use impervious armlength gloves when mixing vaccine in a bucket or header tank. 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 fluoroquinolones (ciprofloxacin).

Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.

Care should be taken to wash and disinfect hands after handling poultry faeces, particularly in the first 14 days after vaccination of birds. Personnel involved in attending vaccinated birds should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling litter from recently vaccinated birds.

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

The veterinary medicinal product should not be administered by pregnant women.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Since the vaccine strain is a live bacterium, simultaneous use of chemotherapeutics which are effective against *Salmonella* should be avoided. However, if this is inevitable, the flock must be re-immunized. A decision to use this vaccine before or after any chemotherapeutic treatment needs to be taken on a case by case basis.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Lohmann Animal Health*-Marek's vaccines (both, Turkeys Herpes Virus and Rispens) and with AviPro SALMONELLA VAC E.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

* Not authorised in all countries

4.9 Amounts to be administered and administration route

For oral use after resuspension in drinking water.

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: A single dose from one day of age.
Birds intended for laying
Layers/Breeders: A single dose from one day of age followed by a second vaccination at 7 weeks of age and a third vaccination at 16 weeks at least 3 weeks before point of lay.

Drinking water

Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap etc.

Use only cold, clean and fresh water, preferably non-chlorinated and free from metal ions.

Open the vaccine ampoule under water and dissolve contents 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.

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. Determine the number of vaccine doses and amount of water (see below) required. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.

As a guide apply diluted vaccine to cold and fresh water at the rate of 1 litre 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– grams per litre) or skimmed milk (20-40 ml/litre of water) to increase the stability of the vaccine.
The admixture should be added to the vaccine in any case 10 minutes before. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.

Allow water in the drinkers to be consumed so that levels prior to vaccine application are minimal. If water is still present the lines must be drained before applying the vaccine. The vaccine treated water should be applied for up to 4 hours. It should be ensured that all birds drink during this period. Birds drinking behaviour 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.

Ideally vaccine should be administered in the volume of water consumed by the birds in up to 4 hours.
In case of doubt the water absorption must be determined the day before vaccination.

- Administer the dissolved vaccine to birds immediately.
- Make sure that birds do not have access to unmedicated water during vaccination.
- Avoid exposure of the vaccine suspension to sunlight.

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

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

4.11 Withdrawal period(s)

Meat, offal and eggs: 21 days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live bacterial vaccines.

ATCvet code: QI01AE01.

To stimulate active immunity against *Salmonella* Typhimurium, phage type 204.
The vaccine strain is a natural metabolic drift mutant of *Salmonella* Typhimurium phage type 9, that is it lacks or does not express certain metabolic pathways which result in attenuation.
The genetic basis results in defective gyrase affecting DNA replication (nalidixic acid 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 sensitive to fluoroquinolones and unlike field strains is sensitive to erythromycin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine
HEPES buffer
Soy peptone
Sucrose

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after reconstitution according to directions: 4 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Boxes of glass bottles of pharmaceutical glass, class I.
They are closed with stoppers of chlorobutyl rubber (type I) and sealed with colour-coded aluminium caps.

Vials of 500, 1,000, 1,500, 2,000, 2,500 doses.

Packs of 2 or 10 by 500, 1,000, 1,500, 2,000, 2,500 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 00879/4190

9. DATE OF FIRST AUTHORISATION

10 October 2002

10. DATE OF REVISION OF THE TEXT

December 2020

Approved 16 December 2020