SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Vac T Lyophilisate for use in drinking water.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substance:

Salmonella Typhimurium, strain Nal 2/Rif 9/Rtt, live attenuated 1 x 10^8 to 6 x 10^8 CFU*

*CFU = Colony Forming Units

Excipients:

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

White to gray-brown pellet

3. CLINICAL INFORMATION

3.1 Target species

Chickens (future breeders and layers, broilers).

3.2 Indications for use for each target species

Active immunisation of chickens from one day old to reduce mortality, colonisation, shedding and faecal excretion of *Salmonella* Typhimurium.
Onset of immunity: within 15 days of first vaccination.
Duration of immunity: 50 weeks in layers and breeders following the three dose regimen, and for at least 6 weeks in broilers after one vaccination.

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 sensitive to fluoroquinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol, doxycycline, detergents and environmental noxae.

Vaccinated birds may excrete the vaccine strain up to 14 days following vaccination. The vaccine strain can spread to susceptible birds in contact with vaccinated chickens.

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.

The differentiation between vaccine and field strains is made by means of an antibiogram. 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).

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. Use impervious arm length 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 waste and bedding materials 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:
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

Since the vaccine strain is a live bacterium, simultaneous use of chemotherapeutics which are effective against *Salmonella* should be avoided.

However, if treatment with chemotherapeutics 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 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.

3.9 Administration routes and dosage

For oral use after resuspension in drinking water.

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: A single dose from one day of age.

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 onset 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 completely by rinsing it 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 – 4 g 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, birds should consume the vaccine that was reconstituted in drinking water within 4 hours.

In case of doubt, the water consumption must be determined on 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.

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, offal and eggs: 21 days.

4. IMMUNOLOGICAL INFORMATION

4.1 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 lacks or does not express certain metabolic pathways, which results 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

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

5.3 Special precautions for storage

Store and transport refrigerated (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 and sealed with aluminium tear-off crimp caps.

Pack sizes:
Cardboard box with 1 vial with 500, 1,000, 1,500, 2,000, 2,500 doses.
Cardboard box with 10 vials with 500, 1,000, 1,500, 2,000, 2,500 doses.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 00879/3033

8. DATE OF FIRST AUTHORISATION

10 October 2002

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

May 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 14 May 2024