SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Duo 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*
- *Salmonella enterica*, subsp. enterica, serovar Typhimurium, strain Nal2/Rif9/Rtt, 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
Sucrose
Glycerol
HEPES buffer

White grey to white brown pellet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers), turkeys (future breeders and turkeys for meat production), ducks (for meat production).

3.2 Indications for use for each target species

Chickens (breeders and layers):
For active immunisation of healthy and susceptible chickens to reduce faecal excretion and colonisation of internal organs with *Salmonella* Enteritidis and *Salmonella* Typhimurium field strains and to reduce colonisation of eggs with *Salmonella* Enteritidis field strains.

Onset of immunity: 15 days after first vaccination.
Duration of immunity:
After 3rd vaccination when used according to the recommended vaccination schedule:

52 weeks against virulent *S*. Enteritidis and 46 weeks against virulent *S*. Typhimurium

After 4th vaccination when used according to the recommended vaccination schedule:
50 weeks against virulent *S*. Enteritidis and 44 weeks against virulent S. Typhimurium

Turkey future breeders and turkeys for meat production:
For active immunisation of healthy and susceptible turkeys to reduce colonisation of internal organs with *Salmonella* Enteritidis and *Salmonella* Typhimurium field strains.

In general, the colonisation of internal organs of vaccinated turkeys with challenge bacteria is reduced compared to unvaccinated turkeys; a statistically significant reduction could not be shown in all instances.

Onset of immunity: 21 days after first vaccination.
Duration of immunity:
Future breeders: 30 weeks against virulent *Salmonella* Enteritidis and 28 weeks against virulent *Salmonella* Typhimurium from the time of the last vaccination when used according to the recommended vaccination schedule.
Turkeys for meat production: 10 weeks against virulent *Salmonella* Enteritidis and against virulent *Salmonella* Typhimurium from the time of the last vaccination when used according to the recommended vaccination schedule.

Ducks for meat production:
For active immunisation of healthy and susceptible ducks to reduce colonisation of internal organs with *Salmonella* Typhimurium field strains.

Onset of immunity: 22 days.
Duration of immunity: 43 days.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

In chickens, protection in the presence of maternally derived antibodies has been shown with a vaccine containing *Salmonella* Enteritidis but no information is available on the *Salmonella* Typhimurium component.

In turkeys, the influence of maternally derived antibodies was not studied.
The prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in commercial turkey holdings can vary widely amongst the European Union Member States. The vaccine should only be used on turkey farms with known occurrence of *Salmonella* Enteritidis or *Salmonella* Typhimurium unless national *Salmonella* control programs in European Union Member States promote control measures such as vaccination.

In ducks, the maternally derived antibodies may have an impact on the development of the immune response.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the vaccine strains for at least 42days following the first and second vaccination. For the *S.* Enteritidis vaccine strain, no excretion and no organ spread could be detected after the third and fourth vaccination. For the *S.* Typhimurium vaccine strain, extended excretion up to 19 weeks after the third vaccination may be possible. No spread to organs including the oviduct was observed from two weeks after the third vaccination. No excretion or organ spread of the *S.* Typhimurium vaccine strain could be detected after the fourth vaccination.

Vaccinated ducks may excrete the *Salmonella* Enteritidis vaccine strain up to 14 days and the *Salmonella* Typhimurium vaccine strain up to 28 days following vaccination.
Shedding of *Salmonella* vaccine strains in turkeys is intermittent. After vaccinated once at the first day of life, duration of excretion was observed for the *Salmonella* Enteritidis vaccine strain up to day 49 and for the *Salmonella* Typhimurium vaccine strain up to day 63. After repeated vaccinations duration of excretion is shortened. Due to limited data, the eggs of vaccinated turkey breeders are not intended for human consumption.

Not tested on ornamental and pure-bred poultry.
The vaccine can spread to susceptible birds in contact with vaccinated birds.
On very rare occasions, the vaccine strains may be isolated from the environment beyond the above-mentioned period when using very sensitive detection methods.

Ensure that the drinking water is free of detergents, disinfectants and acids.

The vaccine strains are highly sensitive to fluoroquinolone antibiotics and have increased sensitivity to erythromycin, chloramphenicol, doxycycline, detergents and environmental noxae.

The differentiation between the vaccine and field strains is achieved by means of an antibiogram:

- *Salmonella* Enteritidis:

In contrast to field strains, the vaccine strain is sensitive to erythromycin (recommended concentration 15–30 µg/ml) and resistant to streptomycin (recommended concentration 200 µg/ml) and rifampicin (recommended concentration 200 µg/ml).

- *Salmonella* Typhimurium:

In contrast to field strains, the vaccine strain is sensitive to erythromycin (recommended concentration 15–30 µg/ml) and resistant to nalidixic acid (recommended concentration 20 µg/ml) and rifampicin (recommended concentration 200 µg/ml).

The vaccine strains 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 authorisation holder.

Depending on the test system used, oral vaccination may result in low seropositive reactions of individual birds in a flock. Since the serological monitoring of *Salmonella* is only a flock test, 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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Open the vial only under water to avoid aerosols.
Wash and disinfect 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 strains are sensitive to a number of antibiotics including quinolones (ciprofloxacin).

Since the 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.

Vaccinated animals may excrete the vaccine strains. Immunocompromised persons are advised to avoid contact with the vaccine and recently vaccinated animals.

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

Personnel involved in attending vaccinated animals should follow general hygiene principals (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding material from vaccinated chickens up to 19 weeks after vaccination, from vaccinated ducks until 28 days after vaccination and from vaccinated turkeys until 63 days after vaccination.

Special precautions for the protection of the environment:

Not applicable.

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 chickens within 3 weeks before the onset of the laying period. Can be used during lay when following the recommended vaccination scheme.
Do not use in ducks intended for lay.

Do not use in turkeys in lay and within 5 weeks before the onset of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

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

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medical 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

In drinking water use.

Advice on correct administration:

The contents of opened vial should be used completely.
Prepare only the amounts of the vaccine that will be used within 4 hours.
Protect the reconstituted vaccine from direct sunlight, frost and temperatures above 25 °C.
Follow these instructions for correct administration, so that all birds receive the appropriate dose.

Vaccination scheme:

AviPro Salmonella Duo may be used from the first day of life.

Ducks for meat production: A single dose from first day of life.

Chickens (breeders and layers): A single dose from first day of life followed by a second vaccination at an age of 6 to 8 weeks and a third vaccination around the 16th week of life at least 3 weeks before onset of lay. A fourth vaccination is recommended during the laying period around the 50th week of life to provide extended protection.

Turkeys for meat production: A single dose from the first day of life followed by a second vaccination at an age of 6 weeks.

Turkey future breeders: A single dose from the first day of life followed by a second vaccination at an age of 6 weeks, a third vaccination at an age of 16 weeks and a fourth vaccination at an age of 23-24 weeks.

Administration via the drinking water:

1. Determination of the required amount of water:

    - Ideally the vaccine should be administered in the volume of water consumed by the birds within 3 hours. Use water meter recording for the previous day to

accurately determine the correct quantity of water in each case. Alternatively, the amount of water needed can be calculated out of the number and age of birds combined with the information given in the water consumption tables from the breeding companies.

- Under hot climatic conditions and in heavy breeds or species other than chickens, especially in the case of older turkeys, this amount might need to be increased to ensure sufficient water uptake of each bird.

2. Resuspension of the lyophilisate:

- The whole content of a vial should be used for one house or drinking system as splitting may lead to dosing errors.
- All equipment used for the vaccination (pipes, hoses, tubes, etc.) should be thoroughly cleaned and free of detergent and disinfectant residues.
- Use only cool, clean and fresh water, preferably free of chlorine and metal ions. Skimmed milk powder (<1% fat) (2–4 grams per litre of water) or skimmed milk (20–40 ml per litre of water) can improve the quality of tap water and thus the stability of the vaccine. However, this has to be done at least 10 minutes prior to adding the vaccine.
- Open the vaccine vial 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. Vaccine solution must be stirred thoroughly for several minutes before administration.

3. Application of the resuspended vaccine:

- 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 time. Due to the varying drinking behaviour of chickens, it might be necessary to withhold water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period.
- A period of thirst of up to 2–3 hours before vaccination might be necessary to ensure that every bird receives a vaccine dose.
- Make sure that birds do not have access to unmedicated water during vaccination.

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

No adverse reactions were observed after administration of a tenfold overdose.

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

For chickens:
meat, offal and eggs: 21 days after the 1st, 2nd and 3rd vaccination; zero days after the 4th vaccination.
For ducks: meat, offal and eggs 21 days
For turkeys: meat and offal: 70 days after the first vaccination,
49 days after repeated vaccination.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI01AE01, QI01BE, QI01CE.

AviPro Salmonella Duo stimulates active immunity against *Salmonella* Enteritidis and against *Salmonella* Typhimurium.

The vaccine strains are natural metabolic drift mutants, i.e. they lack or do not express genes of certain metabolic pathways which result in attenuation.

The genetic basis results in defective ribosomal protein S12 affecting polypeptide synthesis (streptomycin resistance), defective gyrase affecting DNA replication (nalidixic acid resistance) and defective RNA polymerase affecting transcription of DNA to RNA (rifampicin resistance).

The vaccine strains also have mutations that increase the permeability of the cell membrane for harmful agents such as detergents and antibiotics. This means that the strains have poor survival in the environment and are highly sensitive to fluoroquinolones and in contrast to field strains are sensitive to erythromycin.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

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 direct sunlight.

5.4 Nature and composition of immediate packaging

Type I (Ph. Eur.) 20 ml glass vials with welt edge and type I rubber stopper. The vials are sealed with aluminium tear-off caps.

The vaccine is available in the following pack sizes:

Cardboard box with 1 vial containing 1 000, 2 000 or 4 000 doses.
Cardboard box with 10 vials containing of 1 000, 2 000 or 4 000 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 GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5070

8. DATE OF FIRST AUTHORISATION

22 July 2011

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

December 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.

Approved 07 January 2026

Gavin Hall