

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Duo lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

One dose contains:

Salmonella enterica, subsp. enterica, serovar Enteritidis, strain Sm24/Rif12/Ssq, Live
min. $1 \times 10^{8.0}$ CFU and max. $6 \times 10^{8.0}$ CFU

and

Salmonella enterica, subsp. enterica, serovar Typhimurium, strain Na12/Rif9/Rtt, Live
min. $1 \times 10^{8.0}$ CFU and max. $6 \times 10^{8.0}$ CFU.

3. PACKAGE SIZE

1,000 doses

2,000 doses

4,000 doses

10 x 1,000 doses

10 x 2,000 doses

10 x 4,000 doses

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use after resuspension in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period:

For chicken and ducks: meat, offal and eggs: 21 days.

For turkeys: meat and offal: 70 days after the first vaccination,
49 days after repeated vaccination.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted, use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from direct sunlight.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/4188

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS – Glass vials**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Duo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Salmonella Enteritidis, strain Sm24/Rif12/Ssq, Live *Salmonella* Typhimurium, strain Nal2/Rif9/Rtt, Live

1,000 doses, 2,000 doses, 4,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro Salmonella Duo lyophilisate for use in drinking water

2. Composition

One dose contains:

Active substances:

- *Salmonella enterica*, subsp. *enterica*, serovar Enteritidis, strain Sm24/Rif12/Ssq,
Live min. 1×10^8 CFU* and max. 6×10^8 CFU*

- *Salmonella enterica*, subsp. *enterica*, serovar Typhimurium, strain Nal2/Rif9/Rtt,
Live min. 1×10^8 CFU* and max. 6×10^8 CFU*

*CFU – colony forming units.

White grey to white brown pellet.

3. Target species

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

4. Indications for use

Chickens (future breeders and future layer hens):

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.

Duration of immunity: 52 weeks against virulent *S. Enteritidis* and 46 weeks against virulent *S. Typhimurium* from the time of the last vaccination when used according to the recommended vaccination schedule.

Turkey 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.

5. Contraindications

None.

6. Special warnings

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.

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the *Salmonella* Enteritidis vaccine strain up to 21 days and the *Salmonella* Typhimurium vaccine strain up to 35 days following 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 turkeys for reproduction 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 recently vaccinated chickens until 35 days after vaccination and from vaccinated ducks until 28 days after vaccination and from vaccinated turkeys until 63 days after vaccination.

Laying birds:

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

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.

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-immunized. 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.

Overdose:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

8. Dosage for each species, routes and method of administration

For oral use after resuspension in drinking water.

Dosage and use:

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

Chickens (future breeders and future 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.

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 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.

9. Advice on correct administration

The contents of opened vials 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.

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 birds, 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.

10. Withdrawal periods

For chicken and ducks: meat, offal and eggs: 21 days.
For turkeys: meat and offal: 70 days after the first vaccination,
49 days after repeated vaccination.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 4 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/4188

The vaccine is available in the following pack sizes:

Cardboard box with 1 vial containing 1,000, 2,000 or 4,000 vaccine doses.

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Tel: +44 3308221732

GB: PV.GBR@elancoah.com

Northern Ireland: PV.XXI@elancoah.com

Manufacturer responsible for batch release:

Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven,
Germany

17. Other information

POM-V	Veterinary medicinal product subject to prescription
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Gavin Hall
Approved: 07 February 2025