

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 AND OTHER SUBSTANCES

One dose contains:

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

Live attenuated *Salmonella* Typhimurium bacteria, strain Nal2/Rif9/Rtt, min. $1 \times 10^{8.0}$ CFU and max. $6 \times 10^{8.0}$ CFU.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water

4. PACKAGE SIZE

1,000 doses

2,000 doses

10 x 1,000 doses

10 x 2,000 doses

5. TARGET SPECIES

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

6. INDICATION(S)

Active immunisation of chickens and turkeys against *Salmonella* Enteritidis and *Salmonella* Typhimurium and of ducks against *Salmonella* Typhimurium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use after resuspension in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted, use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Do not freeze.

Protect from direct sunlight.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4188

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro SALMONELLA DUO, lyophilisate for use in drinking water

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose contains:

Live attenuated *Salmonella* Enteritidis bacteria, strain Sm24/Rif12/Ssq, $1 \times 10^{8.0}$ - $6 \times 10^{8.0}$ CFU

and

Live attenuated *Salmonella* Typhimurium bacteria, strain Nal2/Rif9/Rtt, $1 \times 10^{8.0}$ - $6 \times 10^{8.0}$ CFU.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses

2,000 doses

4. ROUTE OF ADMINISTRATION

For oral use after resuspension in drinking water.

5. WITHDRAWAL PERIOD

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.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

United Kingdom

PACKAGE LEAFLET FOR:

AviPro SALMONELLA DUO lyophilisate for use in drinking water

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Marketing Authorisation Holder:

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

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro SALMONELLA DUO lyophilisate for use in drinking water

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

One dose contains:

Active substances:

Live attenuated *Salmonella* Enteritidis bacteria, strain Sm24/Rif12/Ssq, min. 1×10^8 CFU* and max. 6×10^8 CFU*

and

Live attenuated *Salmonella* Typhimurium bacteria, strain Nal2/Rif9/Rtt, min. 1×10^8 CFU* and max. 6×10^8 CFU*

*CFU – colony forming units.

Excipients:

Soy peptone
Sucrose
Gelatine
HEPES buffer.

Appearance:

White grey to white brown pellet.

4. INDICATIONS

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: for 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.
for 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. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (future breeders and future layer hens), turkey breeders and turkeys for meat production and ducks for meat production, from one day old.

8. DOSAGE FOR EACH SPECIES, ROUTE 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 layer hens): 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.

Oral administration via the drinking water

1. Determination of the required amount of water:

- 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 applied for up to 3 hours, ensuring 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 plain (vaccine free) water during vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

The contents of opened bottles 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.

10. 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.

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 stated on the label.

Shelf life after reconstitution according to directions: 4 hours.

12. SPECIAL WARNINGS

Special warnings for each target species:

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 use in animals:

Vaccinate healthy animals only.

Not tested on ornamental and pure-bred poultry.

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.

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).

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 litter from 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.

Lay:

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 other veterinary medical product. A decision to use this vaccine before or after any other veterinary medicinal product therefor needs to be made on a case-by-case basis.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Cardboard box with 1 vial containing 1,000 vaccine doses.

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

Bundle packs:

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

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

Not all pack sizes may be marketed.

Approved 16 December 2020

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.