

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro SALMONELLA VAC T
Lyophilisate for use in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

1 dose contains:

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

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.

4. PACKAGE SIZE

500, 1,000, 1,500, 2,000, or 2,500 doses

5. TARGET SPECIES

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

6. INDICATION(S)

For active immunisation of chickens to reduce mortality, colonisation, shedding and faecal excretion of *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: Meat, offal and eggs: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP

Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local requirements.

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

Distributor:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4190

17. MANUFACTURER’S BATCH NUMBER

Batch.....

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro SALMONELLA VAC T
Lyophilisate for use in drinking water.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance:

1 dose contains:

At least 1×10^8 to 6×10^8 CFU live attenuated *Salmonella* Typhimurium bacteria,
strain Nal 2/Rif 9/Rtt.

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

500, 1,000, 1,500, 2,000, or 2,500 doses

4. ROUTE(S) OF ADMINISTRATION

For oral use after resuspension in drinking water.

5. WITHDRAWAL PERIOD

Withdrawal Period: Meat, offal and eggs: 21 days.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP

Once reconstituted use within 4 hours.

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

AviPro SALMONELLA VAC T
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, IF DIFFERENT

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 VAC T
Lyophilisate for use in drinking water

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:

1 dose contains:

At least 1×10^8 to 6×10^8 CFU live attenuated *Salmonella* Typhimurium bacteria,
strain Nal 2/Rif 9/Rtt.

*CFU = Colony Forming Units

Appearance: White to gray-brown pellet.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None.

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

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

1. Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap etc.
2. Use only cold, clean and fresh water, preferably non-chlorinated and free from metal-ions.
3. 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.
4. 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.
5. 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 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.

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.

6. 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat, offal and eggs: 21 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Protect from light.

Do not use after the expiry date stated on the label.

Shelf-life after reconstitution according to directions: 4 hours

12. SPECIAL WARNING(S)

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

Furthermore pay attention that the tap water does not contain any detergents or disinfectants.

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

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.

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 reimmunized. 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

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).

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.

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

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.