ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Vac T Lyophilisate for use in drinking water.

2. STATEMENT OF ACTIVE SUBSTANCE

1 dose contains:
Salmonella Typhimurium, strain Nal 2/Rif 9/Rtt, live attenuated 1×10^8 to 6×10^8 CFU

3. PACKAGE SIZE

1 vial of 500 doses
10 vials of 500 doses
1 vial of 1000 doses
10 vials of 1000 doses
1 vial of 1500 doses
10 vials of 1500 doses
1 vial of 2000 doses
10 vials of 2000 doses
1 vial of 2500 doses
10 vials of 2500 doses

4. TARGET SPECIES

Chickens (future breeders and layers, broilers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use after resuspension in drinking water.

7. WITHDRAWAL PERIODS

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

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 light.

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 00879/3033

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Vac T

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Salmonella Typhimurium, strain Nal 2/Rif 9/Rtt, live attenuated

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviPro Salmonella Vac T Lyophilisate for use in drinking water.

2. Composition

One dose contains:

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

*CFU = Colony Forming Units

White to gray-brown pellet

3. Target species

Chickens (future breeders and layers, broilers).

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 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).

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 from recently vaccinated birds.

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.

Laying birds:
Do not use in birds in lay and within 3 weeks before the start of the laying period.

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 chemotherapeutic treatment 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 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.

Overdose:
There were no undesired effects after application of the 10-fold dose.

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

7. Adverse events

Chickens:
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.

8. Dosage for each species, routes 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 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.

9. Advice on correct administration

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 completely by rinsing it 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 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.
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.

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.

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 periods

Meat, offal and eggs: 21 days.

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 light.

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 00879/3033

The vaccine is available in the following pack sizes:
Cardboard box with 1 vial with 500, 1,000, 1,500, 2,000 or 2,500 doses.
Cardboard box with 10 vials with 500, 1,000, 1,500, 2,000 or 2,500 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

Manufacturer responsible for batch release:
Lohmann Animal Health GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

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