

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE} Box

To be supplied only on veterinary prescription.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro® SALMONELLA VAC E

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES, COMPOSITION

1 dose contains:

At least 1×10^8 CFU attenuated *Salmonella* Enteritidis bacteria, strain Sm24/Rif12/Ssq.

3. PHARMACEUTICAL FORM

Freeze-dried live vaccine for reconstitution in drinking water.

4. PACKAGE SIZE

500, 1,000, 1,500, 2,000, 2,500, 3,000, 3,500, 4,000, 4500, and 5,000 doses.

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

For active immunisation of healthy susceptible, immune competent chickens to reduce mortality, colonisation, invasion and faecal excretion due to *Salmonella* Enteritidis, phage type 4.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration via the drinking water.

8. WITHDRAWAL PERIOD

Withdrawal: 21 days.

9. SPECIAL WARNING(S), IF NECESSARY

Follow DIRECTIONS FOR USE.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C). Do not freeze. Protect from light.
In-use shelf-life: 4 hours after dissolution.

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

Disposal see leaflet.

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

FOR ANIMAL TREATMENT ONLY

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

Vm 00879/4189

17. MANUFACTURER’S BATCH NUMBER

LOT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro Salmonella Vac E

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose contains:

At least 1×10^8 CFU attenuated *Salmonella* Enteritidis bacteria, strain
Sm24/Rif12/Ssq

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

1,000 doses

2,000 doses

5,000 doses

4. ROUTE(S) OF ADMINISTRATION

For oral administration via the drinking water.

5. WITHDRAWAL PERIOD

Withdrawal period: 21 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

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

PACKAGE LEAFLET

AviPro® SALMONELLA VAC E

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 E

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

1 dose contains:

At least 1×10^8 CFU attenuated *Salmonella* Enteritidis bacteria, strain Sm24/Rif12/Ssq

Freeze-dried live vaccine for reconstitution in drinking water.

4. INDICATION(S)

For active immunisation of healthy susceptible, immune competent chickens to reduce mortality, colonisation, invasion and faecal excretion due to *Salmonella* Enteritidis, phage type 4.

Immunity develops within 14 days of vaccination and remains for 6 to 8 weeks following a single dose and for 60 weeks following the 3 dose programme.

5. CONTRAINDICATIONS

Do not vaccinate sick birds. Do not vaccinate birds in lay. Vaccination of birds intended as laying birds must be completed 3 weeks before point of lay.

6. ADVERSE REACTIONS

Not known.

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

7. TARGET SPECIES

Chickens

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

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: | For birds up to 6 weeks of age, a single dose at one day of age. |
| Layers and Breeders: | A single dose from one day of age followed by a second vaccination at 6 to 8 weeks of age and a third vaccination at 16-18 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. Open the vaccine ampoule 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.
3. 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. Do not split large vials to vaccinate more than 1 house or drinking system, as this leads to mixing errors.
4. As a guide apply diluted vaccine to cold and fresh water at the rate of 1 liter 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 liter) or skimmed milk (20-40 ml per litre of water) to increase the stability of the vaccine. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.
5. 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 period. Birds drinking behavior 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

Special precautions for use in animals

The vaccine strain is supersensitive to quinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol, doxycycline, detergents and environmental noxae.

The differentiation between vaccine and field strains is done by means of an antibiogramme. In contrast to field strains, vaccine strains are sensitive to erythromycin (recommended concentration 15-30 µg/ml) and resistant to streptomycin and rifampicin (recommended concentration 200 µg/ml).

The presence of maternal antibodies to *Salmonella* Enteritidis may reduce the effect of vaccination over the first 4 days of life.

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 have to be confirmed, e.g. by bacteriology.

Antibacterials shall not be administered 3 days before and after immunization.

If antibiotic treatment is inevitable, the respective animals must be re-immunized, however, not earlier than three days after this treatment.

Day old chicks may be vaccinated with AviPro® SALMONELLA VAC E by the oral route and Marek's vaccine (both turkey herpes and Rispens) by injection.

AviPro® SALMONELLA VAC E may be administered on the same day as AviPro® SALMONELLA VAC T, but not simultaneously.

As no data is available for other vaccines do not use within 14 days of any other vaccine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Use gloves when reconstituting the vaccine. Open vial under water to avoid aerosols. Disinfect and wash hands after handling vaccine. Do not ingest. If the vaccine has been swallowed seek medical advice. The vaccine strain is sensitive to a number of antibiotics including quinolones (ciprofloxacin).

Care should be taken to wash and disinfect hands after handling poultry faeces, particularly in the first 7 days after vaccination of birds.

Operators should not handle vaccine if known to be suffering from immunosuppressive disease.

10. WITHDRAWAL PERIOD

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.

Shelf life after dissolution: 4 hours

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

12. SPECIAL WARNING(S)

Do not mix with any other immunological products.

Do not vaccinate sick birds. Do not vaccinate birds in lay. Vaccination of birds intended as laying birds must be completed 3 weeks before point of lay.

The vaccine strain may spread to susceptible birds in contact with vaccinates. Studies have shown that vaccinated birds shed the vaccine strain for up to 16 days.

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

Destroy the unused live vaccine or reconstituted vaccine with disinfectant before disposal.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

Legal category POM-V

Reg No.: Vm 00879/4189

The vaccine is available in the following packaging sizes:

Box with vial with 1,000 doses

Box with ten vials with 1,000 doses

Box with vial with 2,000 doses

Box with ten vials with 2,000 doses

Box with vial with 5,000 doses

Box with ten vials with 5,000 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.