[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviPro SALMONELLA VAC E Lyophilisate for use in drinking water for chickens (DE+AT)
AviPro SALMONELLA VAC E Lyophilisate for use in drinking water (BE, BG, CY, CZ, EE, EL, ES, FR, HR, HU, IT, LT, LV, NL, PL, PT, RO, SI, SK)

2. QUALITATIVE AND QUANTITATIVE 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*.

*CFU – colony forming units.

Excipients:

Qualitative composition of excipients and other constituents
Gelatine
HEPES buffer
Peptone
Sucrose

White to greyish/ brownish lyophilised pellet

3. CLINICAL INFORMATION

3.1 Target species

Chickens (future breeders and layers).

3.2 Indications for use for each target species

Active immunisation of chickens to reduce the number of *Salmonella* Enteritidis field strains excreting birds.
Onset of immunity: 15 days.
Duration of immunity: 52 weeks from the time of the last vaccination when used according to the recommended vaccination schedule.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Not tested in ornamental and pure-bred poultry.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain is highly sensitive to quinolone 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.

The differentiation between vaccine and field strains is done by means of an antibiogram. 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 vaccine strain 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 serological Salmonella monitoring is a flock test only, 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:

Use gloves when reconstituting the vaccine. Open vial under water to avoid aerosols. 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 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. 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 materials from recently vaccinated birds.

Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during the excretion of the vaccine strain.

The veterinary medicinal product should not be administered by pregnant women.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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 treatment with chemotherapeutics is inevitable, the flock must be re-immunized. A decision to use this vaccine before or after any chemotherapeutic treatment needs to be decided on a case-by-case basis.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal 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.

3.9 Administration routes and dosage

In drinking water use.

Dosage and use:
One dose should be administered per animal.
The vaccine may be used from the 1st day of life.

Recommended vaccination scheme:
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 onset of lay.

Drinking water:
Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap etc..

Use only cool, clean and fresh water, preferably free of chlorine and metal ions.

Open the vaccine ampoule under water and dissolve thoroughly. As the concentrated vaccine is slightly viscous, care should be taken to empty the ampoule completely by rinsing it in water. 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.

As a guide apply diluted vaccine to cold and fresh water at the rate of 1 litre of water per 1000 birds per day of age e.g. 10 litres would be needed for 1000 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 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.

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 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 21 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code :

QI01AE01

To stimulate active immunity to *Salmonella* Enteritidis, phage type 4.
The vaccine strain is a natural metabolic drift mutant, that lacks or does not express certain metabolic pathways, which results in attenuation.
The genetic basis results in defective ribosomal protein S12 affecting polypeptide synthesis (streptomycin resistance) and defective RNA polymerase affecting transcription of DNA to RNA (rifampicin resistance).
The vaccine strain also has attenuations that increase the permeability of the cell membrane for harmful agents such as detergents and antibiotics. This means the strain has poor survival in the environment and is highly sensitive to fluoroquinolones and unlike field strains is sensitive to erythromycin

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 4 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Vials made of type I pharmaceutical glass.
The vials are closed with type I rubber closures and sealed with aluminium tear-off crimp caps.

Pack sizes:
Cardboard box with 1 vial with 1 000, 2 000or 5 000 doses
Cardboard box with 10 vials with 1 000, 2 000or 5 000 doses

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}
To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}.
To be completed nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD month YYYY}
To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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 E
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 1 x 10^8 CFU to 6 x 10^8 CFU.

3. PACKAGE SIZE

1 000 doses
2 000 doses
5 000 doses
10 x 1 000 doses
10 x 2 000 doses
10 x 5 000 doses

4. TARGET SPECIES

Chickens (future breeders and layers)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 21 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
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

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

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 VAC E
Lyophilisate for use in drinking water

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Salmonella Enteritidis, strain Sm24/Rif12/Ssq, Live.

1 000 doses, 2 000 doses, 5 000 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 E
Lyophilisate for use in drinking water for chickens

2. Composition

One dose contains:
Active substances:
Salmonella enterica, subsp. enterica, serovar Enteritidis, strain Sm24/Rif12/Ssq, Live min. 1 x 10^8 CFU* and max. 6 x 10^8 CFU*

*CFU – colony forming units.
White to greyish/ brownish lyophilised pellet

3. Target species

Chickens (future breeders and layers)

4. Indications for use

Active immunisation of chickens to reduce the number of *Salmonella* Enteritidis field strains excreting birds.
Onset of immunity: 15 days.
Duration of immunity: 52 weeks from the time of the last vaccination when used according to the recommended vaccination schedule.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Not tested in ornamental and pure-bred poultry.

Special precautions for safe use in the target species:
The vaccine strain is highly sensitive to quinolone 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.

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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.

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. 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 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. 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 materials from recently vaccinated birds.

Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during the excretion of the vaccine strain.

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 treatment with chemotherapeutics is inevitable, the flock must be re-immunized. A decision to use this vaccine before or after any chemotherapeutic
treatment needs to be decided on a case-by-case basis.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal 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:
There were no undesired effects after application of the 10-fold dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

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: {national system details}

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

In drinking water use.

Dosage and use:
One dose should be administered per animal.
The vaccine may be used from the 1st day of life.

Recommended vaccination scheme:
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 onset of lay.

9. Advice on correct administration

Drinking water:
Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap etc..

Use only cool, clean and fresh water, preferably free of chlorine and metal ions.

Open the vaccine ampoule under water and dissolve thoroughly. As the concentrated vaccine is slightly viscous, care should be taken to empty the ampoule completely by rinsing it in water.

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.

As a guide apply diluted vaccine to cold and fresh water at the rate of 1 litre of water per 1000 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 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.

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 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.

10. Withdrawal periods

Meat and offal: 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 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

MA-No.: To be completed nationally

Pack sizes:
Cardboard box with 1 vial with 1 000, 2 000 or 5 000 doses
Cardboard box with 10 vials 1 000, 2 000 or 5 000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
To be completed nationally.

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