1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviProSALMONELLA VAC E
Lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 dose contains:
1 x 10^8 CFU to 6 x 10^8 CFU attenuated Salmonella Enteritidis-bacteria, strain Sm24/Rif12/Ssq.

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension
White to greyish/ brownish lyophilised cake

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce the number of Salmonella Enteritidis field strains excreting birds.
Immunity develops within 14 days of first vaccination: after 15 days the faecal excretion is reduced up to 70 %.
The immunity lasts until 52. week of life.

4.3 Contraindications

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

4.4 Special warnings <for each target species>

Not tested in ornamental and pure-bred poultry.
Not to be used in chickens during lay.
The vaccine may spread to susceptible birds in contact with vaccinates. Vaccinated birds shed the vaccine strain for up to 14 days.
Bell drinkers are preferred during first days of life, the use of nipple drinkers for one day old chickens can only be recommended if used according to national regulations.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine strain is highly sensitive 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 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).

Vaccinate healthy birds only.

Depending on the test system used, oral vaccination may result in low seropositve 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. 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 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 this 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 taking into account that the vaccination protects the animals from 14 days after the first vaccination.

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).
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 decided on a case by case basis.
*(Not registered in all countries).

4.9 Amounts to be administered and administration route

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

Layers and Breeders: A single dose at 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
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 and its top completely by rinsing them 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 grams 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat and offal: 21 days.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01AE01

To stimulate active immunity to Salmonella Enteritidis, phage type 4.
The vaccine strain is a natural metabolic drift mutant, i.e. is it lacks or does not express certain metabolic pathways which result 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peptone
Sucrose
Gelatine
HEPES-buffer

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. Furthermore pay attention that the tap water does not contain any detergents or disinfectants.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months
Shelf-life after dilution or reconstitution according to directions: 4 hours

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Glass (type I) bottles,
closed with stoppers of chlorobutyl rubber (type I) and sealed with colour-coded aluminium caps.

The following pack sizes are registered:
1 x 1000/ 2000/ 5000 doses
10 x 1000/ 2000/ 5000 doses

Not all pack sizes may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Lohmann Animal Health GmbH
Heinz-Lohmann-Str. 4
D-27472 Cuxhaven, Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Germany: July 19th, 1999, renewal July 22nd, 2004

10 DATE OF REVISION OF THE TEXT

January 2020