ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN SALMONELLA E Lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Live, attenuated *Salmonella enterica* subsp. ***enterica*** serovar Enteritidis-strain CAL 10 $Sm^+/Rif^+/Ssq^-$,1-6 x 10^8 CFU*

*CFU: Colony Forming Units

Excipients:

Qualitative composition of excipients and other constituents
Skimmed milk
Sucrose
Gelatin
HEPES buffer
Water for injections

Lyophilisate for use in drinking water.

Appearance: white-beige to white-brown pellet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (replacement chicks (future layers and breeders))

3.2 Indications for use for each target species

Active immunisation to reduce colonisation of internal organs (spleen, liver, caeca and ovaries) and faecal excretion of *Salmonella* Enteritidis field strains.

Onset of immunity: within 14 days after 1st vaccination and within 4 weeks after the 2nd and 3rd vaccination.

Duration of immunity: until 80 weeks after the 3rd vaccination, and until 40 weeks after the 4th vaccination, when used according to the recommended vaccination schedule.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.
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).
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 for safe use in the target species

Not tested in ornamental and pure-bred poultry.
The vaccine strain may spread to susceptible birds in contact with vaccinates. Vaccinated birds shed the vaccine strain until 14 days after the vaccination.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

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

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Open bottle 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 14 days after vaccination of birds.
Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during handling and 28 days following vaccination.

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 its local representative> or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds

Do not use in birds within 3 weeks before the start of the laying period. Can be used during lay.

3.8 Interaction with other medicinal products and other forms of interaction

The vaccine strain is highly sensitive to chemotherapeutics as quinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol and doxycycline detergents and environmental noxae. This product can be administered 3 days after or before the administration of these chemotherapeutics which are effective against *Salmonella*. If this is inevitable, the flock must be re-immunized.

The efficacy of this product can be compromised by the simultaneous use of Gumboro, Eimeria and Marek live vaccines. For this reason, a case-by-case evaluation by the responsible veterinarian regarding the administration of other vaccines before and after of this immunological product during the first days of life, is recommended. The repeated use of the Salmonella Enteritidis vaccine in later phases (booster vaccinations) could solve these negative interactions when used in day-old chickens in combination with other vaccines.

3.9 Administration routes and dosage

One dose should be administered per animal.

The vaccine may be used as from the 1st day of life (during the first 36 hours of life).

Recommended vaccination scheme:

Dosage Regimen

Replacement chicks (Future 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 15-20 weeks at least 3 weeks before the onset of the laying period. A fourth vaccination during laying period can optionally be used at 55 weeks to reduce caeca colonization and excretion of field strains.

Advice on correct administration via drinking water:

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

Use only fresh drinking water, free of chlorine and metal ions.

Open the vaccine bottle under water and dissolve thoroughly in a 1 litre vessel half full and stir well before mixing with more water. As the concentrated vaccine is slightly viscous, care should be taken to empty the bottle and its top completely by rinsing them in water. Then add water until 1 litre in the same recipient. Vaccine must be stirred thoroughly for several minutes at each stage. Do not split large bottles to vaccinate more than 1 house or drinking system, as this leads to mixing errors.

As a guide apply the reconstituted vaccine to cold and fresh water at the rate of 1 litre of drinking water per 1,000 1-day-old chicks, 25-35 litres of water per 1,000 6-8 week-old birds. 35-40 litres of water per 1,000 15-20 week-old birds and at least 60 litres of water per 1,000 55 week-old birds.

Use water meter recordings for the previous day to determine accurately the correct quantity of water in each case.

Low fat skimmed milk powder (i.e.<1 % fat) is recommended to 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 water with vaccine.

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 within 3 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, antidotes)

No adverse reactions were detected after a 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 after 1st, 2nd and 3rd vaccination.
Meat and offal: 14 days after 4th vaccination.
Eggs: zero days after 4th vaccination.

4. IMMUNOLOGICAL INFORMATION

Pharmacotherapeutic group: "Live bacterial vaccine (*salmonella*) for domestic fowls"

ATCvet 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. 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 medical product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 3 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

20 ml colourless glass vials of hydrolytic glass type I (Ph. Eur.) with 1,000, 2,000 or 4,000 doses.

The vials are closed with bromobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:

Cardboard box with 1 vial (20 ml) of 1,000 doses

Cardboard box with 1 vial (20 ml) of 2,000 doses

Cardboard box with 1 vial (20 ml) of 4,000 doses

Cardboard box with 10 vials (20 ml) of 1,000 doses

Cardboard box with 10 vials (20 ml) of 2,000 doses

Cardboard box with 10 vials (20 ml) of 4,000 doses

Not all pack sizes may be marketed.

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

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

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7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 23/01/2015

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

MM/YYYY

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.