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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water
Appearance: Spongy white-beige to white-brown pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (future layers and breeders)

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce colonisation of internal organs (spleen, liver, caeca and ovaries) and faecal excretion of *Salmonella* Enteritidis field strains.
Onset of immunity: 14 days after 1st vaccination and 4 weeks after the 3rd vaccination.
Duration of immunity: 80 weeks after the 3rd vaccination, when used according to the recommended vaccination schedule.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
The efficacy of the vaccine has not been investigated in the presence of maternally derived antibodies.

4.5 Special precautions for use

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 use in animals

Not tested in ornamental and pure-bred poultry.
The vaccine strain may spread to susceptible birds in contact with vaccinates by shedding. Vaccinated birds shed the vaccine strain until 21 days after the first vaccination. Susceptible birds in contact with vaccinates after the first vaccination may shed the vaccine strain until 14 days after vaccination. Level and duration of spread of the vaccine strain markedly decreases with subsequent vaccinations. 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). The vaccine strain can be found in the environment for up to 14 days. Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.
Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during handling and 28 days following vaccination.

Special precautions for the protection of the environment:

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 section 16 of the package leaflet for contact details.

4.7 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.

4.8 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-immunised.
The efficacy of this product can be compromised by the simultaneous use of live vaccines against Gumboro disease, *Eimeria* and Marek disease. 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.

4.9 Amount(s) to be administered and administration route

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 (during the first 36 hours of life).

Recommended vaccination scheme:
Dosage regimen
Chickens (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.

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 diluted vaccine to cold and fresh water at the rate of 1 litre of drinking water per 1,000 birds per day of age, for 6–8-week-old chicks: 25-35 litres of water per 1,000 birds, for 15–20-week-old birds: 35-40 litres of water per 1,000 birds. 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 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.
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.

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

There were no adverse reactions after application of the 10-fold dose.

4.11 Withdrawal period(s)

Meat and offal: 28 days after 1st, 2nd and 3rd vaccination.

5. IMMUNOLOGICAL PROPERITES

Pharmacotherapeutic group: Immunologicals for Aves, live bacterial vaccines for domestic fowls.
ATCvet code: QI01AE01 (*Salmonella*).

To stimulate active immunity to *Salmonella* Enteritidis, phage type 4. The vaccine strain is a natural metabolic drift mutant, i.e., 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

Skimmed milk
Sucrose
Gelatin

HEPES buffer
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medical product.

6.3 Shelf life

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

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 of 1,000 doses
Cardboard box with 1 vial of 2,000 doses
Cardboard box with 1 vial of 4,000 doses
Cardboard box with 10 vials of 1,000 doses
Cardboard box with 10 vials of 2,000 doses
Cardboard box with 10 vials of 4,000 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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

Vm 20634/5002

9. DATE OF FIRST AUTHORISATION

26 March 2024

10. DATE OF REVISION OF THE TEXT

March 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 26 March 2024