SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN SALMONELLA T 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 Typhimurium, strain ST CAL 16 $Str^+/Rif^+/Enr^-$ $1\text{-}6 \times 10^8$ CFU*

* CFU: Colony forming units

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

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 (future layers and breeders) to reduce faecal excretion and colonisation of internal organs with Salmonella Typhimurium field strains.
Onset of immunity: 14 days after first vaccination.
Duration of immunity: 61 weeks after the third 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.

4.5 Special precautions for use

The vaccine strain is highly sensitive to quinolone antibiotics and has increased sensitivity to enrofloxacin, 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 enrofloxacin (recommended concentration 0.5 µg/ml) and resistant to streptomycin (recommended concentration 50-100 µg/ml) and rifampicin (recommended concentration 5-10 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
Vaccinated chickens may excrete the vaccine strain up to 28 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species. An effective rodent control program should be established, as infected mice may also spread the vaccine strain.

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 the vaccine vials 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 can be found in the environment for up to 28 days. 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 animal waste and bedding materials from recently vaccinated birds.
Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during 28 days after vaccination.
The veterinary medicinal product should not be administered by pregnant women.

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 the last section of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Laying birds
The safety of the veterinary medicinal product has not been established during lay.
Do not use in birds in lay and within 4 weeks before the start of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

Since the vaccine strain consists of live bacteria, no antimicrobials should be used within 3 days before and after immunisation with the vaccine. However, if this is inevitable, the flock must be re-immunised. A decision to use this vaccine before or after any chemotherapeutic treatment needs to be taken 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, so 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.

4.9 Amount(s) to be administered and administration route

For oral use after resuspension in drinking water.
Recommended vaccination scheme:
One dose from one day of age (in the first 72 hours), followed by a second vaccination at 6 to 8 weeks of age and a third vaccination at 14-18 weeks at least 4 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 cold, clean and 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 vessel. The vaccine must be stirred thoroughly for several minutes at each stage. Do not split large bottles to vaccinate more than 1 poultry house or drinking system, as this leads to dosing errors.
As a guide apply the reconstituted vaccine to cold and fresh water at a 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 and 35-40 litres of water per 1,000 14-18 week-old 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) 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. 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 ready-to-use vaccine solution should be consumed within 3 hours. It should be ensured that all birds drink during this period. Birds drinking behaviour varies. Therefore, 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 apply every bird one dose of vaccine. A period of thirst of up to 2-3 hours depending on the actual climatic conditions before vaccination may be necessary to achieve this.

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

No adverse reactions were detected after a 10-fold dose.

4.11 Withdrawal period

Meat and offal: 28 days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, live bacterial vaccine for domestic fowls.
ATCvet code: QI01AE01.

Primun Salmonella T stimulates active immunity to *Salmonella* Thyphimurium.
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 enrofloxacin.

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 and transport refrigerated (2 ^{o}C – 8 ^{o}C).
Protect from light.

6.5 Nature and composition of immediate packaging

Type I (Ph. Eur.) colourless glass vials (20 ml) containing 1,000 doses or 2,000 doses. They 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 10 vials (20 ml) of 1,000 doses.
Cardboard box with 10 vials (20 ml) of 2,000 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

Laboratorios Calier, S.A.
C/Barcelones 26 (Pla del Ramassa)
08520 Les Franqueses del Valles
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 20634/5000

9. DATE OF FIRST AUTHORISATION

28 November 2023

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.
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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 28 November 2023