**PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN SALMONELLA E Lyophilisate for use in drinking water for chickens.

## 2. 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

Lyophilisate for use in drinking water

Appearance: white-beige to white-brown pellet.

## 3. TARGET SPECIES

Chickens (replacement chicks (future layers and breeders))

## 4. INDICATIONS FOR USE

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 3rdvaccination, and until 40 weeks after the 4th vaccination, when used according to the recommended vaccination schedule.

## 5. CONTRAINDICATIONS

None.

## 6. SPECIAL WARNINGS

Special warnings

Vaccinate healthy animals only

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 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 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.

Laying birds

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

Interactions 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.

Overdose

There were no undesired effects after application of a10-fold dose.

Major incompatibilities

Do not mix with any other veterinary medical product.

## 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><the local representative of

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

One dose should be administered per animal.

The vaccine may be used as from the 1st day of life (during the first 36 hour 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:**

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 recommende 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.

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 10. 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.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 ºC – 8 ºC).

Do not freeze

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after dilution in water according to directions: 3 hours

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

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. These measures should help to protect the environment.

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation numbers

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.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## 16. CONTACT DETAILS

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS CALIER, S.A.

c/o. Barcelonés 26, Pla del Ramassà
08520 Les Franqueses del Vallès, BARCELONA, SPAIN
Tel.: +34 (0) 938495133
E-mail: info@calier.es

## 17. Other information

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.