PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box (1x1,000, 1x2,000 or 1x4,000 doses)
Cardboard box (10x1,000, 10x2,000doses or 10x4,000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Primun Salmonella E lyophilisate for use in drinking water for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose contains:
Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Enteritidis, strain CAL10 Sm+/RIF+/Ssq-, 1-6x 10^8 CFU*
*CFU: Colony forming units.

3. PACKAGE SIZE

1,000 doses
2,000 doses
4,000 doses
10x1,000 doses
10x2,000 doses
10x4,000 doses

4. TARGET SPECIES

Chickens (future layers and breeders)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use

7. WITHDRAWAL PERIODS

Withdrawal period: meat and offal: 28 days after 1st, 2nd and 3rd vaccination.

8. EXPIRY DATE

<Exp. {mm/yyyy}>
Once reconstituted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 20634/5002

15. BATCH NUMBER

Lot (number)

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM–V ('Veterinary medicinal product subject to prescription')

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml glass vial (of 1,000, 2,000 or 4,000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Primun Salmonella E lyophilisate

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Enteritidis, strain CAL 10 $Sm^+/Rif^+/Ssq^-$,1-6 x 10^8 CFU*
**CFU: Colony forming units*

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}
Once reconstituted use within 3 hours.

5. ROUTE(S) OF ADMINISTRATION

In drinking water use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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
Appearance: spongy white-beige to white-brown pellet

3. TARGET SPECIES

Chickens (future layers and breeders)

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

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

Special precautions for safe use in the target species:
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.
Not tested in ornamental and pure-bred poultry.
The vaccine strain may spread to susceptible birds in contact with vaccinates.
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 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 in lay and at least 3 weeks before the start of the laying period.

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-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.

Overdose:
There were no adverse reactions after application of a 10-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

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 hour 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:
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.

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.
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.

10. WITHDRAWAL PERIODS

Meat and offal: 28 days after 1st, 2nd and 3rd 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. The expiry date refers to the last day of that month.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. 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

Vm 20634/5002

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 REVISED

{MM/YYYY}

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Laboratorios Calier, S.A.
C/Barcelonès 26 (Pla del Ramassà)
08520 Les Franqueses del Vallès
Spain
Tel.: +34 (0) 938495133
E-mail: info@calier.es

Local representatives and contact details to report suspected adverse reactions:

Kernfarm UK Ltd.

32 Victory Boulevard, Lytham St. Annes, England, FY8 5TH

Tel.: +44 7543 556682

Email: qppv@kernfarm.com

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. This means the strain has poor survival in the environment and is highly sensitive to fluoroquinolones and unlike field strains is sensitive to erythromycin.

POM-V ('Veterinary medicinal product subject to prescription')

For animal treatment only.

Approved 26 March 2024