LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml glass vial (1 unit, or 10 units)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN SALMONELLA T 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 Typhimurium, strain ST CAL 16 $Str^+/Rif^+/Enr^-$ 1-6 x 10^8 CFU*

****CFU: Colony Forming Units***

3. PACKAGE SIZE

1,000 doses or 2,000 doses

10 x 1,000 doses or 10 x 2,000 doses

4. TARGET SPECIES

Chickens (future layers and breeders)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use after resuspension in drinking water use

7. WITHDRAWAL PERIODS

Withdrawal period: meat and offal: 28 days.

8. EXPIRY DATE

EXP {mm/yyyy}

Once reconstituted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated

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 20634/5000

15. BATCH NUMBER

Lot (number)

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC 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 or 2,000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN SALMONELLA T lyophilisate for use in drinking water for chickens

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:

Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Typhimurium, strain ST CAL 16 $Str^+/Rif^+/Enr^-$ 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

For oral use after resuspension 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 T lyophilisate for use in drinking water for chickens.

2. COMPOSITION

Each dose contains:

Active substance:

Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Typhimurium, strain ST CAL 16 $Str^+/Rif^+/Enr^-$ 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 (future layers and breeders).

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings

Vaccinate healthy animals only.

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 achieved by means of an antibiogram. In contrast to field strains, the vaccine strain is 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 safe use in the target species

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 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 28 days after vaccination.

The veterinary medicinal product should not be administered by pregnant women.

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.

Interactions 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.

Overdose

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

Major incompatibilities

Do not mix with any other veterinary medical product.

7. ADVERSE EVENTS

None known.

If you notice any serious effects not mentioned in this package leaflet, please inform your veterinary surgeon.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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 but at least 4 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 the solution 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 there is a volume of 1 litre in the same vessel. The vaccine must be stirred thoroughly for several minutes at each stage. Do not split large bottles for use in 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 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.

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 to 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.

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 cold, clean and fresh drinking water, free of chlorine and metal ions.

10. WITHDRAWAL PERIODS

Meat and offal: 28 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ^{o}C – 8 ^{o}C).

Protect from light.

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

Shelf life after reconstitution according to directions: 3 hours

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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 .

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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.

Vm 20634/5000

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/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, manufacturer responsible for batch release:

LABORATORIOS CALIER, S.A.
c/o. Barcelonés 26, Pla del Ramassà
08520 Les Franqueses del Vallès, BARCELONA, SPAIN
Tel.: +34 (0) 938495133
E-mail: pharmacovigilance@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

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

For animal treatment only.

PRIMUN Salmonella T stimulates active immunity against Salmonella Typhimurium.

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 that the strain has poor survival in the environment and is highly sensitive to quinolones and unlike field strains is sensitive to enrofloxacin.

Approved 28 November 2023