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 SUBSTANCES

Each dose contains:

Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Typhimurium bacteria strain ST CAL 16 Str<sup>+</sup>/Rif<sup>+</sup>/Enr<sup>-</sup>,1-6 x 10<sup>8</sup> 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 Read the package leaflet before use.

#### 7. WITHDRAWAL PERIODS

Withdrawal period: meat and offal: 28 days after first and second vaccinations and 14 days after third vaccination.

#### 8. EXPIRY DATE

EXP {mm/yyyy}

### 9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator 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 – to be supplied only on veterinary prescription

### 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

# 15. BATCH NUMBER

Lot (number)

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 bacteria, strain ST CAL 16 Str<sup>+</sup>/Rif<sup>+</sup>/Enr<sup>-</sup>,1-6 x 10<sup>8</sup> CFU\*

\*CFU: Colony Forming Units

### 3. BATCH NUMBER

Lot {number}

# 4. EXPIRY DATE

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