

Primun Salmonella E



Lyophilisate for use in drinking water for chickens

EN Statement of the active substances and other ingredients: Active substance: Each dose contains: Live, attenuated *Salmonella enterica* subsp. *enterica* serovar *Enteritidis*-strain CAL10 Sm+/Rif+/Ssq-, 1-6 x 10⁸CFU*

*CFU: Colonies Forming Unit

Appearance: Spongy white-beige tablet to white-brown pellet.

Indications: Replacement chicks (future layers and breeders): 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 of 1st vaccination and within 4 weeks after the 2nd and 3rd vaccination. Duration of immunity: until 80 weeks after the 3rd vaccination, when used according to the recommended vaccination schedule and until 40 weeks after the 4th vaccination, when used according to the recommended vaccination schedule.

Contraindications: Do not use in unhealthy birds.

Adverse reactions: None known. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system. For details regarding the national system please contact NCA.

Target species: Chickens.

Dosage for each species, routes and method of administration: Dosage and use: 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.

In drinking water use

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 and for 55 week old birds at least 60 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.

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.

Withdrawal period: 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.

Special storage precautions: Keep out of the sight and reach of children. Store in a refrigerator (2°C–8°C). 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.

Special warnings: Special warnings for each target species: 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. **Vaccinate healthy animals only.**

Special precautions for use in animals: Not tested in ornamental and pure-bred poultry. The vaccine strain can 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 bottle 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.

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

Interaction 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, it is recommended 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. The repeated use of the Salmonella Enteritidis vaccine in ulterior phases (booster vaccinations) could solve these negative interactions when used at day old chickens in combination with other vaccines.

Overdose (symptoms, emergency procedures, antidotes), if necessary: There were no undesired effects after application of a 10-fold dose.

Incompatibilities: Do not mix with any other veterinary medical product.

Special precautions for the disposal of unused product or waste materials, if any: Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Other information: Pack sizes: Cardboard box with 1 vial (20 ml) of 1000 doses. Cardboard box with 1 vial (20 ml) of 2000 doses. Plastic box with 10 vials (20 ml) of 1000 doses. Plastic box with 10 vials (20 ml) of 2000 doses. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer responsible for batch release:



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