1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Salmovac Lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substances:
Salmonella enterica, subsp. *enterica*, serovar Enteritidis, strain 441/014 (adenine and histidine auxotrophic), Live 1 - 8 x 10^8 CFU*

** CFU = Colony Forming Unit*

Excipients:

Qualitative composition of excipients and other constituents
Sucrose

Light beige to brownish light grey lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each target species

Active immunisation of chickens from one day of age to reduce colonisation, persistence and invasion of the intestinal tract and internal organs by *Salmonella* Enteritidis and *Salmonella* Typhimurium.

Onset of immunity within 6 days after first vaccination.

Duration of immunity for *Salmonella* Enteritidis is 35 weeks after second vaccination and 63 weeks after third vaccination when used according to the recommended vaccination schedule.

Duration of immunity for *Salmonella* Typhimurium is 60 weeks after the third vaccination when used according to the recommended vaccination schedule.

3.3 Contraindications

Do not use in broilers.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated chickens excrete the vaccine strain up to six weeks following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. The vaccine can spread to susceptible birds. Special precautions should be taken to avoid spreading of the vaccine strain to susceptible birds. Contact chickens may also excrete the vaccine strain.

The vaccine strain has been isolated from chicken litter up to 13 days after vaccination.
In studies, the vaccine strain can be found in the environment for up to 8 weeks after the 2nd vaccination and 5 weeks after the 3rd vaccination.
On very rare occasions, the vaccine strain may be isolated from the environment beyond the above mentioned period.

The vaccine strain has been shown to spread to non-target species such as calves and pigs. It persisted in these animals and was excreted over a period of 9 days in calves and 22 days in pigs and has been shown to cause a transient increase in body temperature.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

The use of the vaccine in fancy breeds has not been studied.

The vaccine strain is among others sensitive to ampicillin, cefotaxime, chloramphenicol, ciprofloxacin, gentamycin, kanamycin, oxytetracycline, streptomycin.
The vaccine strain is resistant to sulfamerazine alone but sensitive to sulfamerazine and trimethoprime in combination.

Due to the adenine-histidine auxotrophy of the vaccine strain, a differentiation between vaccine and field strains is possible by means of an appropriate growth test such as the Ceva S-check test.

A clear differentiation between vaccine strain and wild type strain is also possible on special chromogenic selective media (e.g. ASAP™ media, Biomérieux) due to a different colour of the vaccine colonies versus wild *Salmonella* Enteritidis strains.

The vaccine strain can also be distinguished from field strains by molecular biological methods, such as real time Polymerase Chain Reaction (PCR) and Restriction Fragment Length Polymorphism (RFLP) in Pulsed- field Gel Electrophoresis (PFGE).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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 antibiotics with the exception of sulfamerazine.

Use disposable gloves when reconstituting the vaccine. Wash and disinfect hands after handling vaccine. Do not ingest.

Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during the period of excretion of the vaccine strain.

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 litter from recently vaccinated chickens. Hands should be washed and disinfected after attending vaccinated chickens.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 3 weeks before the start of laying period.
Unvaccinated birds intended for lay should not come into contact with vaccinated birds.

3.8 Interaction with other medicinal products and other forms of interaction

No anti-infective substances should be used within 3 days before and after immunisation with the vaccine. In case of essential administration, the vaccination of the concerned birds has to be repeated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medical product. 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.

No competitive microflora preparations should be administered concurrently with the product.

3.9 Administration routes and dosage

Immunisation against *Salmonella* Enteritidis

Recommended vaccination scheme for birds on farms of unknown *Salmonella* status or positive *Salmonella* Enteritidis detection:
One dose from first day of age, a second dose two weeks later and a third dose not later than three weeks before the laying period. There should be more than two weeks between the second and third administration.

Recommended vaccination scheme for birds on farms with a known history and absence of *Salmonella* Enteritidis according to routine bacteriological monitoring:
One dose from first day of age followed by a second dose two weeks later (but not later than 6 weeks before the onset of lay). A greater level of protection, with regards to the duration of immunity, is observed with the 3-dose regime.

Immunisation against *Salmonella* Enteritidis and *Salmonella* Typhimurium (whatever the salmonella status)

One dose from first day of age, a second dose six weeks later and a third dose around 13 weeks of age.

Administration in drinking water (oral route).

- Apply the usual aseptic precautions to all administration procedures.
- Calculate the number of vials of vaccine required to vaccinate all the birds.
- Use only clean, antiseptic and disinfectant free drinking water.

- Reconstitute the vaccine using a small volume of drinking water in the vaccine vial. Ensure the complete dissolution of the lyophilisate. Then add the reconstituted vaccine to sufficient water to be consumed within 4 hours and mix thoroughly.

Birds may have drinking water withdrawn for 1-2 hours before administering vaccine.

As a guide, administer the vaccine in a volume of at least 2 litres of drinking water per 1 000 chickens at first vaccination and at least 5 litres of drinking water per 1 000 chickens at second vaccination two weeks later.
If a third dose is administered, use at least 10 – 20 litres of drinking water per 1 000 chickens. This third dose should be administered not later than three weeks before the laying period.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of an overdose (10 doses) can occasionally result in loose faeces and in a transient weight loss without any consequences on the final performances.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

The import, sale, supply and/or use of this vaccine is restricted or prohibited in Ireland pursuant to national animal health policy. Any person intending to import, sell, supply and/or use this vaccine must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.

3.12 Withdrawal periods

Meat: 6 weeks
Eggs: 3 weeks

Do not use within 3 weeks before the start of the laying period.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AE01

For active immunisation of chickens against *Salmonella* Enteritidis and *Salmonella* Typhimurium.

The live vaccine strain stimulates cell-mediated immunological mechanisms (as demonstrated in mice) and antibody formation in chickens against *Salmonella* Enteritidis and *Salmonella* Typhimurium. The antibody formation does not affect serological testing for *Salmonella* Gallinarum (rapid serum agglutination).
The vaccine strain is resistant to sulfamerazine. The strain has been demonstrated as genetically stable.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after reconstitution according to directions: 4 hours

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:
Injection vial, 10 ml, glass type I (1000 vaccine doses).
Injection vial, 25 ml, glass type I (2500 vaccine doses).
Injection vial, 100 ml, glass type II (5000 vaccine doses).
Closure for freeze-dried products and caps in compliance with Ph. Eur.

Packaging:
- 1000-dose bottle of lyophilisate: box of 1 bottle
- 1000-dose bottle of lyophilisate: box of 10 bottles.
- 2500-dose bottle of lyophilisate: box of 1 bottle.
- 2500-dose bottle of lyophilisate: box of 10 bottles.
- 5000-dose bottle of lyophilisate: box of 1 bottle.
- 5000-dose bottle of lyophilisate: box of 12 bottles.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Original vaccine containers (opened as well as emptied) and all equipment used for the vaccination procedure have to be disinfected after use (disinfectants - except quaternary ammonium bases - of usual working concentration).

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/063/001

8. DATE OF FIRST AUTHORISATION

05/03/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/01/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).