1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallimune Se + St, water-in-oil emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3 ml dose of vaccine contains:

Active substances:
Salmonella enterica, subsp. enterica, serovar Enteritidis, strain PT4, inactivated .....≥ 171 SAT[1].U[2]
Salmonella enterica, subsp. enterica, serovar Typhimurium, strain DT 104, inactivated ....≥ 149 SAT[1].U[2]
The concentrations are expressed by the antibody titre obtained during the potency test.
[1] SAT: Slow Agglutination Test.
[2] U: one unit corresponding to an antibody titre of 1.

Adjuvant:
Paraffin oil .....q.s. 0.3 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	≤ 30 µg
Formaldehyde	≤ 0.15 mg
Ester of fatty acids and ethoxylated polyol	
Ester of fatty acids and polyols	
Water for injections	

White emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets).

3.2 Indications for use for each target species

For active immunisation of pullets to:
- Reduce *Salmonella* Enteritidis dissemination in the ovary, as demonstrated 4 days after challenge;
  - Onset of immunity: 25 weeks after vaccination.
  - Duration of immunity: 58 weeks of age.
- Reduce *Salmonella* Typhimurium and *Salmonella* Enteritidis dissemination in the intestinal tract.
  - Onset of immunity: 4 weeks after vaccination.
  - Duration of immunity: 61 weeks of age for *Salmonella* Typhimurium and 52 weeks of age for *Salmonella* Enteritidis.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccination causes a serological response in chickens which may interfere with a surveillance program based solely on serological screening without confirmatory bacteriology.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Undetermined frequency (cannot be estimated from the available data):	Injection site lesion[1], Delayed onset of lay[2].

[1]Mild, may occur 3 weeks after injection and may persist through laying period and decline over time.
[2]Slightly delayed onset of lay may occur without impact on peak production or overall egg productivity.

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 its local representative 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 within 2 weeks before the onset of the laying period or during the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with inactivated vaccines for chickens of Boehringer Ingelheim Gallimune range against egg drop syndrome (EDS76), Newcastle disease, infectious bronchitis (Mass41) and avian rhinotracheitis (swollen head syndrome).

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Intramuscular use.
Injection of one dose (0.3 ml) of vaccine, according to the following vaccination scheme:

- first injection: from the age of 6 weeks;
- second injection: at the age of 16 weeks.

The interval between the two injections should be at least 4 weeks and at most 10 weeks.

Shake well before use. The emulsion is homogeneous after shaking.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Equipment including needles and syringes must be sterile before use.

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

In addition to the effects mentioned in paragraph "Adverse events", inflammatory reactions have been observed at the injection site after administration of a double dose of vaccine.

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

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AB01.

Inactivated vaccine in oily adjuvant against *Salmonella* Enteritidis and *Salmonella* Typhimurium.
The vaccine stimulates active immunity of pullets against *Salmonella* Enteritidis and *Salmonella* Typhimurium.
The SE strain is classified as phagotype 4, the ST strain is classified as Definitive Type DT 104.
Although the following has not been investigated, the vaccine may be expected to reduce *Salmonella* Enteritidis transovarian egg contamination and *Salmonella* Typhimurium and *Salmonella* Enteritidis egg shell contamination.

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 first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.
Keep the bottle in the outer carton.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:
- Polypropylene bottle.
- Nitrile elastomer closure.
- Aluminium cap.

Pack sizes:
- Cardboard box with 1 x 300 ml bottle (1 x 1 000 dose).
- Cardboard box with 10 x 300 ml bottles (10 x 1 000 dose).

Not all pack sizes may be marketed.

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

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/054/001

8. DATE OF FIRST AUTHORISATION

22/06/2007

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

12/12/2024

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).