

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 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 ..... $\geq 171 \text{ SAT}^1 \cdot \text{U}^2$

*Salmonella enterica*, subsp. enterica, serovar Typhimurium, strain DT 104, inactivated ... $\geq 149 \text{ SAT}^1 \cdot \text{U}^2$

The concentrations are expressed by the antibody titre obtained during the potency test.

<sup>1</sup> SAT: Slow Agglutination Test.

<sup>2</sup> 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	$\leq 30 \mu\text{g}$
Formaldehyde	$\leq 0.15 \text{ mg}$
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 <sup>1</sup> , Delayed onset of lay <sup>2</sup> .
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<sup>1</sup>Mild, may occur 3 weeks after injection and may persist through laying period and decline over time.

<sup>2</sup>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**

To be completed nationally.

<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must consult the relevant Member State’s Competent Authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>

<Not applicable.>

### **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**

To be completed nationally.

## **7. MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally.

## **8. DATE OF FIRST AUTHORISATION**

{DD/MM/YYYY} To be completed nationally.

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

{DD/MM/YYYY} To be completed nationally.

**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>).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box of 1 bottle of 300 ml (1 000 doses)**  
**Cardboard box of 10 bottles of 300 ml (10 000 doses)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.3 ml dose of vaccine contains:

*Salmonella* Enteritidis, strain PT4, inactivated .....  $\geq 171 \text{ SAT}^1 \cdot \text{U}^2$

*Salmonella* Typhimurium, strain DT 104, inactivated .....  $\geq 149 \text{ SAT}^1 \cdot \text{U}^2$

The concentrations are expressed by the antibody titre obtained during the potency test.

<sup>1</sup>SAT: Slow Agglutination Test.

<sup>2</sup>U: one unit (U) corresponding to an antibody titre of 1.

**3. PACKAGE SIZE**

0.3 ml/d

1 000 doses (300 ml)

10 x 1 000 doses (10 x 300 ml)

**4. TARGET SPECIES**

Chickens (pullets)

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

Shake well before use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: zero days.

**8. EXPIRY DATE**

Exp. {dd/mm/yyyy}

Once opened use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Do not freeze.  
Protect from light.  
Keep the bottle in the outer carton.

**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**

To be completed nationally.

**14. MARKETING AUTHORISATION NUMBERS**

To be completed nationally.

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**300 mL BOTTLES 1 000 DOSES**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Per 0.3 ml dose:

*Salmonella* Enteritidis, strain PT4, inactivated .....  $\geq 171$  SAT.U

*Salmonella* Typhimurium, strain DT 104, inactivated .....  $\geq 149$  SAT.U

0.3 ml/d

300 ml

**3. TARGET SPECIES**

Chickens (pullets)

**4. ROUTES OF ADMINISTRATION**

Intramuscular use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period: zero days.

**6. EXPIRY DATE**

Exp. {dd/mm/yyyy}

Once opened use immediately.

**7. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

Keep the bottle in the outer carton.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

To be completed nationally.

**9. BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

Each 0.3 ml dose of vaccine contains:

*Salmonella enterica*, subsp. *enterica*, serovar Enteritidis, strain PT4, inactivated .....  $\geq 171 \text{ SAT}^1 \cdot \text{U}^2$

*Salmonella enterica*, subsp. *enterica*, serovar Typhimurium, strain DT 104, inactivated ..  $\geq 149 \text{ SAT}^1 \cdot \text{U}^2$

Paraffin oil ..... q.s. 0.3 ml

Thiomersal, .....  $\leq 30 \mu\text{g}$

Formaldehyde .....  $\leq 0.15 \text{ mg}$

The concentrations are expressed by the antibody titre obtained during the potency test.

<sup>1</sup>SAT: Slow Agglutination Test.

<sup>2</sup>U: one unit (U) corresponding to an antibody titre of 1.

White emulsion.

### 3. Target species

Chickens (pullets).

### 4. Indications for use

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.

### 5. Contraindications

None.

### 6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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.

Laying birds:

Do not use within 2 weeks before the onset of the laying period or during the laying period.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that the 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.

Overdose:

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.

Special restrictions for use and special conditions for use:

To be completed nationally.

<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>

<Not applicable.>

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## **7. Adverse events**

Chickens:

**Undertermined frequency (cannot be estimated from the available data):** Injection site lesion<sup>1</sup>, delayed onset of lay<sup>2</sup>.

<sup>1</sup>Mild, may occur 3 weeks after injection and may persist through laying period and decline over time.

<sup>2</sup>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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report

any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

## **8. Dosage for each species, routes and method of administration**

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.

## **9. Advice on correct administration**

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.

## **10. Withdrawal periods**

Zero days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C).

Protect from light.

Do not freeze.

Keep the bottle in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “Exp.”. Shelf-life after first opening the immediate packaging: use immediately.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

To be completed nationally.

Pack sizes:

- Cardboard box with 1 x 300 ml bottle (1 x 1 000 doses)
- Cardboard box with 10 x 300 ml bottles (10 x 1 000 doses)

Not all pack sizes may be marketed.

#### **15. Date on which the package leaflet was last revised**

{DD/MM/YYYY}

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

#### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:  
To be completed nationally.

Manufacturer responsible for batch release:

Boehringer Ingelheim  
Animal Health Italia S.p.A  
Via Baviera 9,  
35027 Noventa Padovana  
Italy

Local representatives and contact details to report suspected adverse reactions:  
To be completed nationally.

#### **17. Other information**

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.