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 .....≥ 171 SAT[1].U[2]
Salmonella 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 (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. {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

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/3039
Vm 08327/5044

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {300 ml Bottles 1000 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 .....≥ 171 SAT[1], U[2]
Salmonella Typhimurium, strain DT 104, inactivated .....≥ 149 SAT[1], U[2]

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. {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

Boehringer Ingelheim Animal Health UK Ltd

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE 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
.....……≥ 171 SAT[1].U[2]
Salmonella enterica, subsp. enterica, serovar Typhimurium, strain DT 104, inactivated
.....≥ 149 SAT[1].U[2]
Paraffin oil .....q.s. 0.3 ml
Thiomersal, ...≤ 30 µg
Formaldehyde .....≤ 0.15 mg
The concentrations are expressed by the antibody titre obtained during the potency test.
[1]SAT: Slow Agglutination Test.
[2]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:
Not applicable

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Vm 08327/3039
Vm 08327/5044

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. PID link (Do not print heading)

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
RG12 8YS
United Kingdom

Manufacturer responsible for batch release:

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

Local representative and contact details to report suspected adverse reactions:

United Kingdom (GB):
Boehringer Ingelheim Animal Health UK Ltd
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

UK(NI) and IE:
Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim am Rhein, Germany.
Tel: +353 1 291 3985

17. Other information

POM-V

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.

Gavin Hall
Approved: 19 May 2025