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:
Inactivated *Salmonella* Enteritidis PT4, at least .....171 SAT.U
Inactivated *Salmonella* Typhimurium DT 104, at least .....149 SAT.U

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

Excipient:
Thiomersal, at most .....30 µg

The concentrations are expressed by the antibody titre obtained during the potency test. One unit (U) corresponding to an antibody titre of 1.
SAT: Slow Agglutination Test .

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Water-in oil emulsion for injection.
White emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (layer pullets).

4.2 Indications for use, specifying the target species

For active immunisation of layer pullets to:
- reduce *Salmonella* Enteritidis dissemination in the ovary, as demonstrated 4 days after challenge;

This has been tested 25 weeks after vaccination and has been demonstrated to persist until 58 weeks of age.
- reduce *Salmonella* Typhimurium and *Salmonella* Enteritidis dissemination in the intestinal tract.

This has been tested 4 weeks after vaccination and has been demonstrated to persist until 61 weeks of age for *Salmonella* Typhimurium and 52 weeks of age for *Salmonella* Enteritidis.

4.3 Contraindications

Please refer to section 4.7 “Use during pregnancy, lactation or lay”.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
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 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 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 product contains mineral oil. Even if small amounts have been injected, accidental injection with this 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.

4.6 Adverse reactions (frequency and seriousness)

No palpable reactions were observed following the injection of one dose of vaccine.
Small lesions linked to the oily adjuvant, e.g. small quantities of oily residues, were observed at the injection site three weeks after the injection and may persist through lay and decline over time.

A slight delay in the onset of lay may be observed, however no impact on peak production or overall egg productivity has been observed.

4.7 Use during pregnancy, lactation or lay

Not to be used within 2 weeks before the onset of the laying period or during the laying period.

4.8 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.

4.9 Amounts to be administered and administration route

Inject by intramuscular route 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.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In addition to the effects mentioned in paragraph “Adverse reactions (frequency and seriousness)”, inflammatory reactions have been observed at the injection site after administration of twice the recommended dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Inactivated vaccine in oily adjuvant against *Salmonella* Enteritidis and *Salmonella* Typhimurium.
The vaccine stimulates active immunity of layer 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.
ATCvet code: QI01AB01.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Thiomersal.
- Formaldehyde.
- Ester of fatty acids and ethoxylated polyols.
- Ester of fatty acids and polyols.
- Water for injections.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product

6.3 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 after opening.

6.4 Special precautions for storage

Store and transport refrigerated between +2°C and +8°C, protected from light.
Do not freeze.
Keep the bottle in the outer carton.

6.5 Nature and composition of immediate packaging

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

Sales presentations:
- 300-ml (1,000-dose) bottle.
- 300-ml (1,000-dose) bottle, box of 10 bottles.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4222

9. DATE OF FIRST AUTHORISATION

11 June 2007

10. DATE OF REVISION OF THE TEXT

November 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of this medicinal product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use this medicinal product must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

Approved: 16 November 2018

D Austin