<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

BOTTLES 1000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.3-ml dose of vaccine contains:
Inactivated *Salmonella* Enteritidis PT4 ≥ .....171 SAT.U
Inactivated *Salmonella* Typhimurium DT 104 ≥.....149 SAT.U
Paraffin oil (as adjuvant) .....q.s. 0.3 ml
Thiomersal ≤ .....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

3. PHARMACEUTICAL FORM

Water-in oil emulsion for injection.

4. PACKAGE SIZE

1000 doses
300 ml

5. TARGET SPECIES

Chickens (layer pullets)

6. INDICATION(S)

In layer pullets, active immunisation against *Salmonella* Enteritidis and *Salmonella* Typhimurium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular route.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

ACCIDENTAL INJECTION IS DANGEROUS - SEE PACKAGE LEAFLET BEFORE USE

10. EXPIRY DATE

EXP
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4222

17. MANUFACTURER'S BATCH NUMBER

Batch:

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

BOTTLES 10*1000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.3-ml dose of vaccine contains:
Inactivated *Salmonella* Enteritidis PT4 ≥ .....171 SAT.U
Inactivated *Salmonella* Typhimurium DT 104 ≥.....149 SAT.U
Paraffin oil (as adjuvant) .....q.s. 0.3 ml
Thiomersal ≤ .....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

3. PHARMACEUTICAL FORM

Water-in oil emulsion for injection.

4. PACKAGE SIZE

10 x 1000 doses
10 bottles of 300 ml

5. TARGET SPECIES

Chickens (layer pullets)

6. INDICATION(S)

In layer pullets, active immunisation against *Salmonella* Enteritidis and *Salmonella* Typhimurium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular route.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

ACCIDENTAL INJECTION IS DANGEROUS - SEE PACKAGE LEAFLET BEFORE USE

10. EXPIRY DATE

EXP
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4222

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLES 1000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallimune Se + St Water-in oil emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per 0.3-ml dose:
Inactivated *Salmonella* Enteritidis PT4 ≥.....171 SAT.U
Inactivated *Salmonella* Typhimurium DT 104 ≥ .....149 SAT.U

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 d
300 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular route.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

Chickens (layer pullets)
Read the package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
GALLIMUNE Se + St

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer for the batch release:
BOEHRINGER INGELHEIM
Animal Health Italia S.p.A
Via Baviera 9,
35027 NOVENTA PADOVANA
ITALIA

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallimune Se + St Water-in oil emulsion for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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
White emulsion.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

7. TARGET SPECIES

Chickens (layer pullets)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

- Vaccinate only healthy animals.
- Do not mix with any other veterinary medicinal product.
- White emulsion, the emulsion is homogeneous after shaking.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated between +2°C and +8°C, protected from light. Do not freeze.
Keep the bottle in the outer carton.
Use immediately after opening.
Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

- Vaccination causes a serological response in chickens which may interfere with a surveillance programme based solely on serological screening without confirmatory bacteriology.
- 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.
- Not to be used within 2 weeks before the onset of the laying period or during the laying period.
- 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.
- 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.
- Do not mix with any other veterinary medicinal product.
- 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

1000-dose bottle
10*1000-dose bottle
Not all pack sizes may be marketed.

For veterinary use only.

To be supplied only on veterinary prescription

POM-V

Vm 08327/4222

Approved: 16 November 2018