Just how far will Merial go for the poultry industry?

Gallimune® Se+St

And the world is safer

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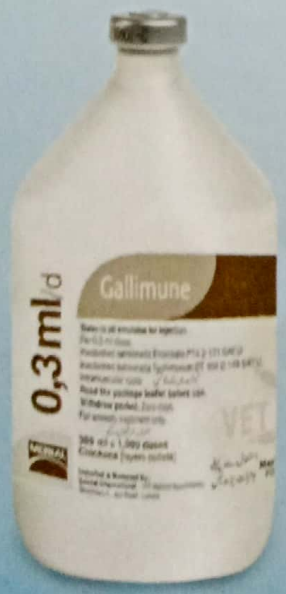
Gallimune® Se+St

SUMMARY

- A BIVALENT, INNOVATIVE AND HIGHLY IMMUNOGENIC VACCINE
- A STRONG AND LASTING SEROCONVERSION
- ...AND THE EGG IS SAFER
- GALLIMUNE® Se + St IN FIVE KEY POINTS

A BIVALENT,

innovative and highly immunogenic VACCINE.



Gallimune® Se + St is a bivalent, inactivated vaccine against *Salmonella* Enteritidis (SE) and *Salmonella* Typhimurium (ST). Indicated for the vaccination of layer pullets, it reduces both transovarian egg contamination (SE) and faecal excretion (SE and ST).

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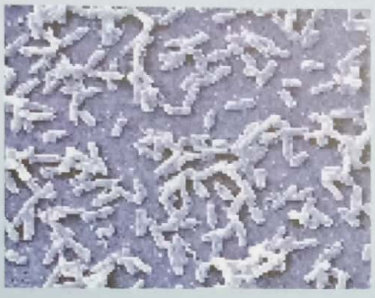
CONTROLLED NUTRIENT FERMENTATION FOR HIGH BACTERIAL DENSITIES WITH PRESERVED ANTIGENICITY

Gallimune® Se+St is the first anti-salmonella vaccine made using an innovative technique with **controlled nutrient fermentation.** This culture process allows to obtain **high bacterial concentrations** without the use of mechanical methods such as centrifugation or microfiltration.

Thanks to this culture method, the bacteria are not physically damaged and **preserve their full immunogenicity**. Bacteria generated by this method keep their typical rod shape and native antigenic expression, while the centrifugation step included in traditional vaccine production methods can deeply alters antigen morphology.

Furtheremore there is less chance to have free LPS, therefore **the risk of endotoxaemic shock** is negligible. The controlled nutrient fermentation has further advantage: high bacterial concentration enables to obtain a high immunogenic level, allowing for **reduced vaccine dose** in volume (0.3ml) and therefore a **lower risk of local reactions.**

Finally, for the production of Gallimune® Se+St entirely **synthetic culture media** are used, without animal or vegetal peptones, thereby eliminating the risk of exogenous contaminations.



Merial internal source

Images from scanning electron microscopy showing cultures of *S. Enteritidis*, obtained by a traditional culture method (at left) and by controlled nutrient fermentation (at right). With this fermentation, the natural morphology, and therefore antigenic expression, of the bacteria remains intact

A BIVALENT, innovative and highly immunogenic VACCINE.

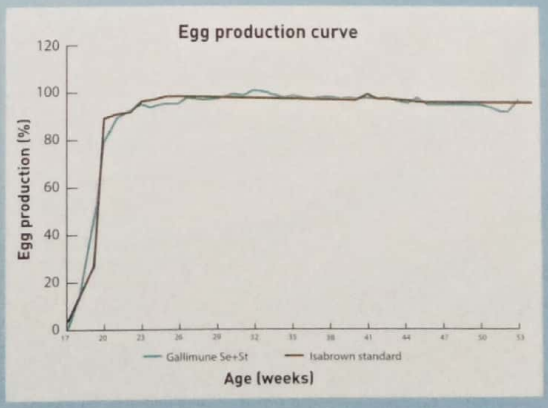
EACH 0.3-ML DOSE OF VACCINE CONTAINS:
INACTIVATED *SALMONELLA ENTERITIDIS* PT4, AT LEAST 421 P.U
INACTIVATED *SALMONELLA TYPHIMURIUM* DT104, AT LEAST 149 SAT.U
THIOMERSAL, AT MOST 30 µG
PARAFFIN OIL (AS ADJUVANT) Q.S. 0.3 ML

A two-dose regimen is recommended for Gallimune® Se+St, with a 4 to 10 weeks' interval: the first injection from the age of 6 weeks, the second at least two weeks before the start of lay.

THE

Gallimune® Se+St offers an excellent alliance between local tolerance and optimal efficacy, thanks to its high antigenic concentration and the limited dose volume of 0.3 ml.

Field studies found no impact on peak production nor on overall egg productivity. Safety: the peak as proof.



Egg production curve obtained in a field trial with Isabrown layers vaccinated with Gallimune® Se+St as compared to the control group: no impact on egg production.
Ref: 03.0882.R

Gallimune® Se+St is furthermore entirely compatible with simultaneous administration of other vaccines of the Gallimune range.

Gallimune® Se+St

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A STRONG AN

Gallimune® **Se+St**

Large-scale field trials have confirmed the safety and efficacy of Gallimune® Se + St, and demonstrated a rapid, strong and lasting seroconversion.
High levels of antibodies persist until the end of lay.

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ID LASTING

seroconv

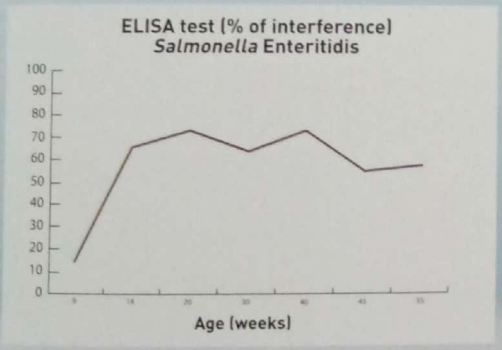
HIGHER ANTIBODY LEVELS

One study measured the levels of anti-H (flagella) and anti-O (cell wall) antibodies to *S.* Enteritidis and *S.* Typhimurium in layers at 21 and 31 weeks of age, using ELISA and sero-agglutination test (SAT).

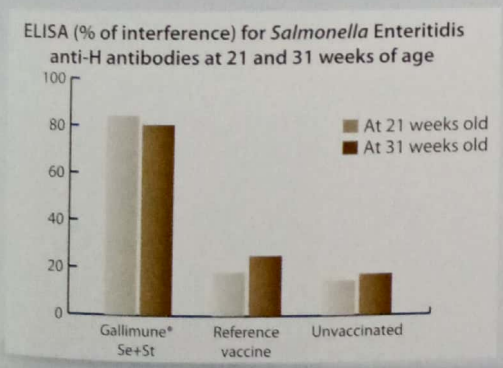
Results showed that immune responses in birds vaccinated with Gallimune® Se+St were **significantly higher** than those in vaccinated with the reference vaccine, or in the controls.

The study also demonstrated that this specific protection lasts **until the end of lay.**

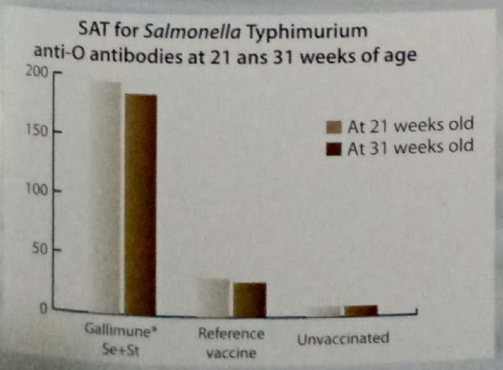
Under recommended vaccine schedules, Gallimune® Se+St induces higher antibody (anti-H and anti-O) levels than the reference vaccine.
This illustrates the superior immunogenic power of the bacterial antigens from the controlled nutrient fermentation process, associated with an oily adjuvant.



Antibody titres against *S.* Enteritidis (H antibodies) as measured with ELISA in laying hens vaccinated with Gallimune® Se+St.
Ref: 03.0882.R - Source : Registration file



Comparison of antibody levels to *S.* Enteritidis (H antibodies) in birds at 21 and 31 weeks of age, vaccinated with either Gallimune® Se+St or the reference vaccine, and controls.
Ref: 04.0242.R - Source : Registration file



Comparison of antibody levels to *S.* Typhimurium (O antibodies) in birds at 21 and 31 weeks of age, vaccinated with either Gallimune® Se+St or the reference vaccine, and controls.
Ref: 04.0242.R - Source : Registration file

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...AND THE EGG

For consumer, protection against *salmonella* can be achieved by reducing the contamination of egg content (ovarian transmission) and of egg shells (faecal shedding).

> *" The aim of vaccination in poultry is both the prevention and reduction of intestinal colonisation resulting in reduced faecal shedding and egg shell contamination and also in the reduced colonisation of reproductive tissues ".*
>
> The EFSA Journal (2004) 114, 1-74

PROTECTING AGAINST THE VERTICAL TRANSMISSION OF *S.* ENTERITIDIS

Salmonella Enteritidis is one of the rare serovars that can systematically infect eggs from the inside. The egg is contaminated before deposition of the shell, by vertical transmission to the contents of the egg (yolk or albumen) via the ovaries and oviductes.

Gallimune® Se+St reduces ovarian infection – and thereby the risk of vertical transmission of *S.* Enteritidis to the egg – by over 90 %.

This was shown in a study on groups of 60 pullets that were vaccinated, either at 10 and 16 weeks of age with a dose (0.3 ml) of Gallimune® Se+St, or at 12 and 16 weeks of age with a dose (0.5 ml) of the reference vaccine, following the manufacturer's recommendations.

This was followed by an oral challenge with a fresh culture of *S.* Enteritidis PT 4 – thereby mimicking a natural infection – at 27 weeks of age.

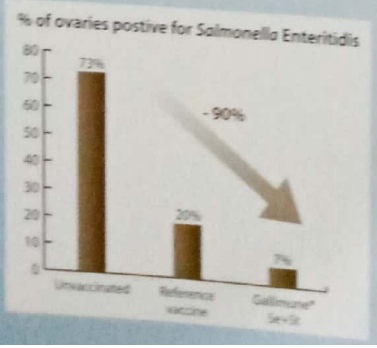
The ovaries were collected four days post challenge.

S. Enteritidis (SE) could be re-isolated in the ovaries of only 7% of the animals vaccinated with Gallimune® Se+St, while SE was found in the ovaries of 20% of birds vaccinated with the reference vaccine (and in 73% of the controls).

The efficacy of Gallimune® Se+St in reducing ovarian infection during the later stages of lay (at 41 and 58 weeks of age) was confirmed by a further study that demonstrated that the protection against ovarian transmission lasts until the end of the laying period.

Gallimune® Se+St provides excellent protection against the vertical transmission of *S.* Enteritidis by reducing ovarian infection.

Gallimune® Se+St provides superior protection against intestinal colonisation and faecal shedding of both *S.* Enteritidis and *S.* Typhimurium.



Results of isolation of *S.* Enteritidis PT4 in the ovaries of birds following oral challenge.
Ref: 04.0720.R

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IS SAFER

REDUCING THE FAECAL SHEDDING OF *S. ENTERITIDIS* AND *S. TYPHIMURIUM*

One of the main routes of transmission of *S.* Enteritidis and *S.* Typhimurium is through contaminated faeces.

In one study, groups of 60 commercial pullets were vaccinated at the age of 10 and 16 weeks with one dose (0.3 ml) of Gallimune® Se+St or at 12 and 16 weeks of age with one dose (0.5 ml) of the reference vaccine, following the manufacturer's recommendations.

The birds were challenged orally with a fresh culture of *S.* Enteritidis PT 4 – thereby mimicking a natural infection – at 29 weeks of age for *S.* Typhimurium and 31 weeks of age for *S.* Enteritidis.

Caecal droppings were collected 4 and 11 days post challenge.

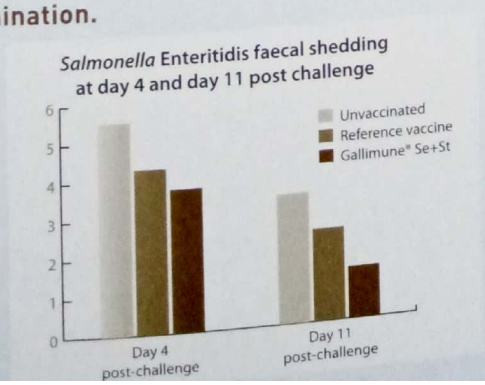
- On day 4, the bacterial counts (log 10) per gram of faeces for *S.* Enteritidis et *S.* Typhimurium were, respectively, 3.76 and 2.69 for Gallimune® Se+St, 4.31 and 4.02 for the reference vaccine and 5.54 and 5.27 for the control birds.
- On day 11, they were 1.37 and 1.65 for Gallimune® Se+St, 2.44 and 1.41 for the reference vaccine and 3.42 and 1.74 for the controls.

Further studies have demonstrated a lasting reduction of faecal excretion in birds vaccinated with Gallimune® Se+St at different stages of the lay.

It has been shown that faecal shedding was reduced:

- At the peak of lay (31 weeks), when challenged with *S.* Typhimurium;
- In the middle of lay (41 weeks), when challenged with *S.* Enteritidis;
- At two thirds of lay (52 weeks), when challenged with *S.* Enteritidis;
- At the end of lay (61 weeks), when challenged with *S.* Typhimurium.

Gallimune® Se+St significantly reduces faecal shedding of *S.* Enteritidis and *S.* Typhimurium - and thereby the risk of egg shell contamination.



ecal shedding of
teritidis on day 4
day 11 post oral
challenge.
Ref: 04.0722.R
04.0721.R

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Gallimune® Se+St

in FIVE key points

1. Bivalent vaccine with an oily adjuvant, against *S.* Enteritidis and *S.* Typhimurium
2. Controlled nutrient fermentation, leading to:
   - a native bacillary shape
   - preserved antigenicity
   - a small vaccine dose (0.3 ml) with maximum efficacy
   - excellent tolerance
3. Rapid, strong and lasting seroconversion for measurable protection
4. Reduction of ovarian infection by over 90%
5. Major reduction of faecal shedding

MERIAL *is part of*
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