Nobilis® SALENVAC® ETC

Salenvac® ETC is the first commercial vaccine to protect against Group B, C and D *Salmonella* serogroups. The two-dose vaccination is formulated to offer broader protection and cause fewer reactions than other *Salmonella* vaccines. Security for your flock, food and way of life.

Safe Aluminium Hydroxide Gel Adjuvant

- Safer for birds and handlers
- Causes minimal vaccine reactions compared to oil-based adjuvants
- Leads to improved flock performance and welfare

Advanced Iron Regulated Protein (IRP) technology

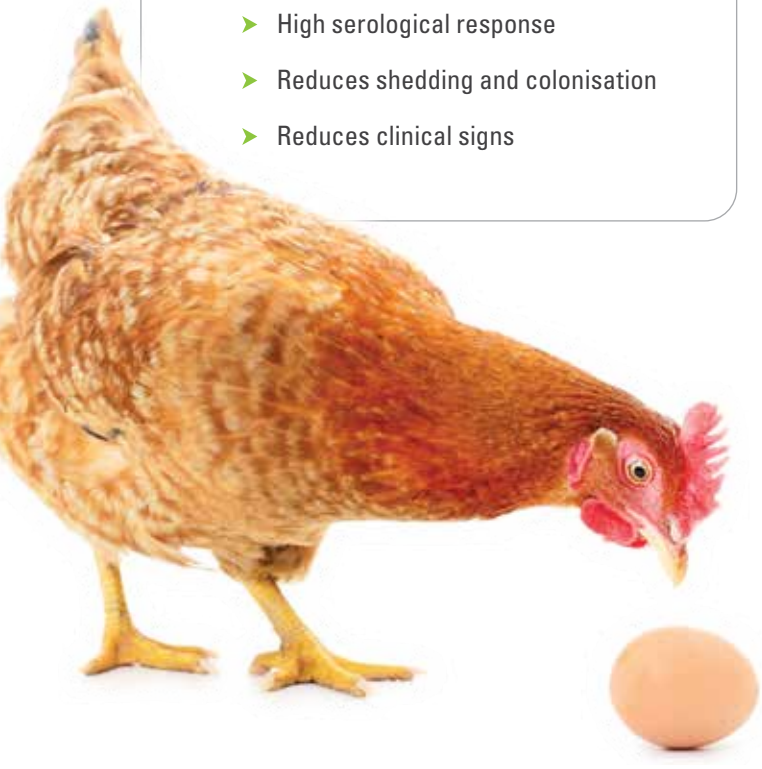
- Vaccine antigen produced under iron restricted conditions results in maximum expression of IRP's
- Induces strong chicken immune response
- Powerful response against a natural field challenge

Optimum immunisation against *Salmonella* spp.

- High serological response
- Reduces shedding and colonisation
- Reduces clinical signs

Broad and Long Protection

- Contains *S. enteritidis, S. typhimurium* and *S. infantis* antigens
- For the active immunisation of chickens to reduce colonisation and faecal excretion of Salmonella Serogroups B, C and D
- Duration of immunity (DOI): 90 weeks after the second administration



Get broad spectrum *Salmonella* control for your flock.

Visit SafePoultry.com to learn more.

MSD Animal Health

Nobilis® SALENVAC® ETC

Nobilis Salenvac ETC suspension for injection for chickens

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

Marketing authorisation holder:
The national representative of
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac ETC suspension for injection for chickens

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

Each dose of 0.5 ml contains:

Active substances:

Inactivated *Salmonella* Enteritidis, strain PT4:	1 – 6.6 RP*
Inactivated *Salmonella* Typhimurium, strain DT104:	1 – 16.1 RP
Inactivated *Salmonella* Infantis, strain A, S03499-06:	1 – 26.6 RP

*RP (relative potency): Ratio of antigenic mass (in Units) as compared to the antigenic mass (in Units) of a reference batch which was shown to be efficacious in chickens.

Adjuvant:

Aluminium hydroxide:	125 mg

Excipients:

Thiomersal:	0.065 mg

Suspension for injection.
A homogeneous, cream to mid-brown suspension.

4. INDICATION(S)

For the active immunisation of chickens from 6 weeks of age to reduce colonisation and faecal excretion of *S.* Enteritidis (serogroup D), *S.* Typhimurium and *S.* Heidelberg (serogroup B), *S.* Infantis, *S.* Hadar and *S.* Virchow (serogroup C).

Onset of immunity after the second vaccination

– *S.* Enteritidis, *S.* Typhimurium, *S.* Infantis, *S.* Hadar and *S.* Virchow: 4 weeks

– *S.* Heidelberg: 9 weeks*

**Earliest timepoint investigated*

Duration of immunity after the second vaccination

– *S.* Enteritidis: 48 weeks (evidenced by challenge) and 90 weeks (evidenced by serology)

– *S.* Typhimurium: 57 weeks (evidenced by challenge) and 90 weeks (evidenced by serology)

– *S.* Infantis: 51 weeks (evidenced by challenge)

– *S.* Hadar: 51 weeks (evidenced by challenge)

– *S.* Virchow: 51 weeks (drawn from scientific reasoning)

– *S.* Heidelberg: 57 weeks (drawn from scientific reasoning)

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Vaccination may very commonly result in small (up to 8 mm in size) and transient palpable nodules at the injection site. These nodules completely disappear within 2 weeks after the second vaccination.

Vaccination may very commonly be associated with mild transient systemic effects such as reduced activity and food intake lasting up to 2 days after the first vaccination.

The frequency of adverse reactions is defined using the following convention:

– very common (more than 1 in 10 animals treated displaying adverse reaction(s))

– common (more than 1 but less than 10 animals in 100 animals treated)

– uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

– rare (more than 1 but less than 10 animals in 10,000 animals treated)

– very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (breeders and layers).

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

Intramuscular injection of one dose of 0.5 ml from 6 weeks of age followed by a second vaccination with one dose of 0.5 ml at least 4 weeks later. The second vaccination should be administered no later than 3 weeks before the onset of lay.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use. Syringes and needles must be sterile before use. Follow standard aseptic procedures.

Hygiene measures and good husbandry practices should also play an important part of a control programme to reduce the incidence of *Salmonella* infection.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species: Vaccinate healthy animals only.

Special precautions for use in animals: Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals: In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

Lay: Do not use in birds in lay and within 3 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes): No data available.

Incompatibilities: Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Pack size: Cardboard box with 1 bottle of 500 ml (1000 doses).

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