SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac ETC suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (breeders and layers).

4.2 Indications for use, specifying the target species

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)

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

Very common (>1 animal / 10 animals treated):	Decreased activity[1]; Reduced food intake[1]; Injection site nodule[2]

[1] May last up to 2 days after the first vaccination
[2] ≤ 8 mm in size; may be present up to 2 weeks after the second vaccination

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to

either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used 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.

4.9 Amount(s) to be administered and administration route

For intramuscular use.

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

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.

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

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for *Aves*, inactivated bacterial vaccine (salmonella) for domestic fowls, Salmonella.

ATCvet code: QI01AB01

To stimulate active immunity to *S.* Enteritidis (serogroup D), *S.* Typhimurium and *S.* Heidelberg (serogroup B), *S.* Infantis, *S*. Hadar and *S*. Virchow (serogroup C).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Tris (trometamol)
Maleic acid
Sodium chloride
Thiomersal
Water for injections

6.2 Major 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: 3 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Protect from light.
Keep the bottle in the outer box.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottle containing 1000 doses of vaccine. The bottle is closed with a halogenobutyl stopper and sealed with an aluminium cap.

Pack sizes:
Cardboard box with one bottle of 500 ml (1000 doses).

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5016

9. DATE OF FIRST AUTHORISATION

18 May 2020

10. DATE OF REVISION OF THE TEXT

September 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved: 03 January 2025