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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.065 mg
Tris (trometamol)	
Maleic acid	
Sodium chloride	
Water for injections	

A homogeneous, cream to mid-brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each 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)

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

3.6 Adverse events

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.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No data available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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).

5.5 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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name} *[To be completed nationally]*

7. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. *[To be completed nationally]*

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac ETC suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (0.5 ml):

S. Enteritidis, strain PT4, inac	1 - 6.6 RP*
S. Typhimurium, strain DT104, inac	1 - 16.1 RP
S. Infantis, strain A, S03499-06, inac	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.

3. PACKAGE SIZE

500 ml (1000 doses)

4. TARGET SPECIES

Chickens (breeders and layers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}*[To be completed nationally]*

14. MARKETING AUTHORISATION NUMBERS

[To be completed nationally]

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label - Low density polyethylene bottle (500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac ETC suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

500 ml (1000 doses)Per dose (0.5 ml):

S. Enteritidis, strain PT4, inac	1 - 6.6 RP*
S. Typhimurium, strain DT104, inac	1 - 16.1 RP
S. Infantis, strain A, S03499-06, inac	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.

3. TARGET SPECIES

Chickens (breeders and layers).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name} *[To be completed nationally]*

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis Salenvac ETC suspension for injection for chickens

2. 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

A homogeneous, cream to mid-brown suspension.

3. Target species

Chickens (breeders and layers).

4. Indications for use

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. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Laying birds:
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:
No data available.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

For intramuscular use.

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. Advise 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 periods

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 immediate packaging: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[MA numbers to be completed nationally]

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

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)

16. Contact details

Marketing authorisation holder:
[To be completed nationally]

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

Contact details to report suspected adverse reactions:
[To be completed nationally]

17. Other information

[To be completed nationally where applicable]

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle boxed area