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.

4.6 Adverse reactions (frequency and seriousness)

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 feed 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).

4.7 Use during pregnancy, lactation or lay

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 Amounts to be administered and administration route

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

Pharmaceutical group: Immunological for Aves, inactivated bacterial vaccine (salmonella) for domestic fowls, Salmonella.
ATC vet 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 injection

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: 2 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.

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 a 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

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4613

9. DATE OF FIRST AUTHORISATION

18 May 2020

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020