SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

Active substance:	
Formalin killed cells of *Salmonella* Enteritidis phage type 4	2×10^9
Adjuvant:	
Alhydrogel, (containing 3% aluminium hydroxide)	250 mg
Excipient:	
Thiomersal (preservative)	0.13 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens: - layers and breeders

4.2 Indications for use, specifying the target species

For the active immunisation of poultry against *Salmonella* Enteritidis, to reduce shedding of *S.* Enteritidis into the environment.
Antibodies against *S.* Enteritidis develop within a few weeks of the second vaccination.
A second peak is achieved shortly after a third vaccination. These antibodies have been shown to persist for at least 60 weeks. Passive immunity will be transferred via the egg to the progeny for at least 57 weeks.

4.3 Contraindications

Do not use in laying birds.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
Cross reactions in tests for *S.* Pullorum are possible but at a low level and may be distinguished from true infection when dilutions of sera are tested, or following heat inactivation. Where serology is positive for *S.* Pullorum, the diagnosis should be confirmed by bacteriology. Hygienic measures and monitoring should not be neglected.

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

4.6 Adverse reactions (frequency and seriousness)

The vaccine contains an adjuvant and may cause a temporary nodule at the site of injection, up to 5 mm in diameter, lasting for up to 2 to 3 days.

4.7 Use during pregnancy, lactation or lay

Do not use in laying birds.

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

Dose
0.1ml to day-old chicks followed by 0.5ml at 4 weeks of age and a booster dose of 0.5ml at 18 weeks of age.

Administration is by intramuscular injection.

The recommended vaccination schedule has been shown under experimental conditions to reduce diarrhoea, excretion of *Salmonella* Enteritidis PT4, infection of certain tissues and egg contamination by *Salmonella* Enteritidis PT4 following challenge. No data are available on these effects in field conditions. Experimentally, it has also been shown that a schedule of two doses of 0.5ml by intramuscular injection, administered respectively at 12 and 16 weeks of age, can produce similar results, but the contamination of eggs has only been investigated in a study involving small numbers.

The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. The instructions supplied with such equipment should be noted and care should be taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

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

The vaccine has been shown to be safe at twice the recommended dose. No effects other than those recorded following administration of one dose were observed.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Salmonella* Enteritidis
Inactivated bacterial vaccine. ATC vet code: QI01AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Tris
Maleic acid
Sodium chloride
Formaldehyde
Thiomersal
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Unopened: 3 years.
Use broached vials immediately.
Partly used packs should be safely destroyed at the end of a day's operations as puncture of the rubber caps could cause accidental contamination of the remaining contents.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C)

Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Carton box with low density multidose polyethylene containers of 250ml and 500ml sealed with an aluminium cap over a rubber stopper. Containers and closures conform to Ph.Eur.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4389

9. DATE OF FIRST AUTORISATION

28 April 1995

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020