PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per ml:
S. Enteritidis PT 4 2 x 10^9 cells

Aluminium hydroxide
Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

250 ml and 500 ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

Vaccination against *Salmonella* Enteritidis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Please read the package leaflet for details on use, warnings and disposal.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Please read the package leaflet for details on use, warnings and disposal.
[*only mentioned once, see section 7*]

10. EXPIRY DATE

EXP {month/year}
Use broached vials immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C - 8 °C)
Protect from light.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please read the package leaflet for details on use, warnings and disposal.
[*only mentioned once, see section 7*]

13 THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14 THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4389

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

POM-V
To be supplied only on veterinary prescription

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobilis Salenvac, suspension for injection

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release[1]:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac
Suspension for injection

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

Per ml:

Formalin killed cells of *Salmonella* Enteritidis phage type 4	2 x 10^9
Alhydrogel (adjuvant)	250 mg
Thiomersal (preservative)	0.13 mg

4. INDICATION(S)

For the active immunisation of chickens 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.

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

5. CONTRAINDICATIONS

Do not use in laying birds.

6. ADVERSE REACTIONS

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.
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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens: - layers and breeders

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

Intramuscular injection of 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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use. Observe aseptic precautions.
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.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children

Store and transport refrigerated (2 °C – 8 °C)
Protect from light
Do not freeze

Do not use after the expiry date stated on the label

Use broached containers immediately

12. SPECIAL WARNING(S)

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.

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.

Do not mix with any other veterinary medicinal product.

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Inactivated bacterial vaccine.
ATC vet code: QI01AB01

Pack sizes: 250 ml and 500 ml multidose bottles
Not all pack sizes may be marketed.

For animal treatment only

For further information, please contact the national representative of MSD Animal Health.