PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac T

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

per dose of 0.5 ml:
Active substance(s):

S. Enteritidis PT 4	≥1 RP*
S. Typhimurium DT104	≥1 RP*

*See package leaflet

Adjuvant: aluminium hydroxide Preservative: thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

250 ml and 500 ml bottles

5. TARGET SPECIES

Chickens

6. INDICATION(S)

Vaccination against *S.*Entertidis PT4 and *S.*Typhimurium DT104.

7. METHOD AND ROUTE OF ADMINISTRATION

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

Keep the container together with the leaflet in the carton.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

[only mentioned once, see section 7]

10. EXPIRY DATE

Exp: …
Use broached containers immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport
refrigerated Do not freeze
Protect from light

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

[only mentioned once, see section 7]

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTONS REGARDING SUPPLY AND USE,

For animal treatment only.

14. THE WORDS “KEEP OUT OF REACH AND SIGHT OF CHILDREN”

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4472

17. MANUFACTURER'S BATCH NUMBER

Batch / Lot: …
For animal treatment only

ANNEX B. PACKAGE LEAFLET

Nobilis Salenvac T

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

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

Manufacturer for the batch release[1]:
Intervet International
B.V. 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 T

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

Suspension for
injection.

per dose of 0.5 ml:

Active substance(s):

Inactivated cells of *Salmonella* Enteritidis, strain PT 4 ≥ 1RP*
Inactivated cells of *Salmonella* Typhimurium, strain DT104 ≥ 1RP*

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

Excipients

Adjuvant: aluminium hydroxide	125 mg
Preservative: thiomersal	0.065 mg

* RP = relative potency = mean antibody response in rabbit potency test equal to or greater than a reference batch which was shown to be efficacious in chickens

4. INDICATION(S)

For the active immunisation of chickens and the passive immunisation of the progeny to reduce caecum colonisation and faecal excretion with *S.* Enteritidis and *S.* Typhimurium.

Active immunity:
Onset of immunity: 4 weeks after the second administration
Duration of immunity: until approximately 56-60 weeks of age for chickens vaccinated at 12 and 16 weeks.
Minor indication: In exceptional circumstances chickens from one day of age may be vaccinated in order to protect them in an environment where they are likely to become infected at an early stage in the rearing phase (epidemiologically indicated by recent outbreak of Salmonella or high infection pressure on the site).
Onset of immunity: 4 weeks after the second administration.

Passive immunity:
Onset of immunity: day one after hatching.
Duration of immunity: until 14 days after hatching.
Passive immunity is transferred from 4 weeks after the second vaccination up to 59 weeks of age of the parent bird.

5. CONTRAINDICATIONS

Do not use in laying birds.

6. ADVERSE REACTIONS

The vaccine contains an adjuvant and vaccination may result in temporary swellings at the injection site.

In chickens of 4 weeks of age and above (receiving a dose of 0.5 ml), vaccination may rarely result in transient small palpable nodules at the injection site (reaching a maximum size of 1 cm^2), evident immediately after vaccination and generally lasting only 1-2 days. Vaccination may also be associated with transient dullness, lethargy and lameness, lasting up to 2 days.

In one-day-old chicks (receiving 0.1 ml) the reactions are more noticeable. It should be taken into account that post-vaccination injection site swellings are generally more evident than when administering 0.5 ml to birds of 4 weeks of age or older, and occasionally, the whole thigh may become swollen. These reactions are temporary and in the majority of cases resolved by 7 days.

Exceptionally, a swelling may still be detectable 15 days after inoculation. In addition, after vaccination a significant proportion of the birds may show signs of lethargy, dullness and lameness, and a reduction of weight gain.

After double dose, similar but more pronounced reactions than seen after a single dose may be observed.

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

7. TARGET SPECIES

Chickens (breeders and layers)

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

Standard vaccination:
Intramuscular injection of one dose of 0.5 ml.

For active immunization of layers and breeders:
Two vaccinations, with an interval of four weeks should be given. The recommended age for vaccination is 12 and 16 weeks of age.

Emergency vaccination (when epidemiologically indicated in high-risk environments): Intramuscular injection of one dose of 0.1 ml in one-day-old chicks.
After an interval of 4 weeks a repeat vaccination with a dose of 0.5 ml should be given.

For passive immunization of progeny of breeders:
Two vaccinations, with an interval of at least four weeks should be given. The recommended age for first vaccination is at 6-12 weeks of age and for the second vaccination at 13-16 weeks of age.

In case the induction of active- and passive immunity is intended in breeders and their offspring, the vaccination scheme for active immunization should be followed.

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

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use. Observe aseptic precautions.

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).
Do not freeze.
Protect from light.
Use broached containers immediately.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

No studies have been performed to evaluate the effect of maternally derived antibodies on the response to vaccination.

Therefore, for use in 1 day old chicks, where epidemiologically indicated, only birds from non-vaccinated and non-infected parent flocks should be vaccinated with Salenvac T.

Do not vaccinate birds in lay.

Vaccination causes a serological response in the chickens which may interfere with a surveillance programme based solely on serological screening without confirmatory bacteriology. The vaccine should therefore not be used when serological detection alone is used to assess flocks for infection with *S.* Enteritidis and/or *S.* Typhimurium. Vaccination also may cause cross reactions in the plate agglutination test for *S.* Pullorum/Gallinarum. Specific serological methods or bacteriology should be used for the differential diagnosis.

Do not mix with any other veterinary medicinal product.

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.

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 MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

ATC vet code: QI01AB01
Inactivated bacterial vaccine

For the passive immunisation scheme upon challenge with *S*. Enteritidis or *S*. Typhimurium, no significant reduction of Salmonella positive samples of liver and spleen was demonstrated.

Pack sizes: 250 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.