SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac T Suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml:
Active substances:
Inactivated cells of *Salmonella* Enteritidis, strain PT 4: ≥ 1 RP*
Inactivated cells of *Salmonella* Typhimurium, strain DT104: ≥ 1 RP*

Excipients:
Adjuvant: aluminium hydroxide: 125 mg
Preservative: thiomersal: 0.065 mg

For a list of excipients, see section 6.1.

* 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

3. PHARMACEUTICAL FORM

Suspension for injection

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 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.

4.3 Contraindications

Do not use in laying birds.

4.4 Special warnings

None

4.5 Special precautions for use

i. 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 Nobilis Salenvac T.

ii. 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 leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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 within 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.

4.7 Use during pregnancy, lactation or lay

Do not vaccinate birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

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.

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

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

<u>For active immunisation of layers and breeders:</u>
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.

<u>For passive immunisation of progeny of breeders:</u>
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 immunisation should be followed.

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

Similar reactions to those seen after a single dose (see 4.6), but more pronounced after double dose.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity and passive immunity of the progeny against *S.* Enteritidis and *S.* Typhimurium. 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.
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

Unopenend: 3 years.
Use broached containers immediately

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 01708/4472

9. DATE OF FIRST AUTHORISATION

17 August 2000

10. DATE OF REVISION OF THE TEXT

August 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Nobilis Salenvac T is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Nobilis Salenvac T must consult the relevant Member States competent authorities on the current vaccination policies prior to the import, sale, supply and/or use.

Approved 14 August 2020