

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Salenvac T suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substances:

Inactivated *Salmonella* Enteritidis, strain PT 4: ≥ 1 RP*

Inactivated *Salmonella* Typhimurium, strain DT104: ≥ 1 RP*

* 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

Adjuvant:

Aluminium hydroxide: 125 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.065 mg
Tris	
Maleic acid	
Sodium chloride	
Formaldehyde	
Water for injections	

A homogeneous, cream to mid-brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (for reproduction and layer hen).

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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 chickens from non-vaccinated and non-infected parent flocks should be vaccinated with the veterinary medicinal product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ . Lameness ² . Low weight gain ³ , lethargy ⁴ , dull ⁴ .
Common (1 to 10 animals / 100 animals treated):	Injection site nodule ⁵ .

¹ In one-day-old chickens (receiving a dose of 0.1 ml), the reactions are more evident than in chickens of 4 weeks of age or older (receiving a dose of 0.5 ml), and occasionally, the whole thigh may become swollen. In the majority of cases, these resolve within 7 days. Exceptionally, a swelling may still be detectable 15 days after inoculation.

² Observed in chickens of 4 weeks of age or older (receiving a dose of 0.5 ml), lameness can last up to 2 days.

³ Observed after use in one-day-old chicks (receiving a dose of 0.1 ml).

⁴ Observed in chickens of 4 weeks of age or older (receiving a dose of 0.5 ml), lethargy can last up to 2 days.

⁵ In chickens of 4 weeks of age and above (receiving a dose of 0.5 ml), small palpable injection site nodules are (reaching a maximum size of 1 cm²) evident immediately after vaccination and generally last only 1-2 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Do not use in birds in lay.

3.8 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.

3.9 Administration routes and dosage

Standard vaccination:

Intramuscular injection of one dose of 0.5 ml.

Shake well before use. Observe aseptic precautions.

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 programme to reduce the incidence of *Salmonella* infection.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Similar reactions to those seen after a single dose (see 3.6), but more pronounced after double dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AB01.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Low density polyethylene bottle containing 500 doses (250 ml) or 1000 doses (500 ml). The bottle is closed with a chlorobutyl stopper and sealed with an aluminium cap.

Pack sizes:

Cardboard box with one bottle of 250 ml (500 doses) or 500 ml (1000 doses).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 01708/3044

8. DATE OF FIRST AUTHORISATION

17 August 2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

Approved 05 November 2024

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