

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis Salenvac T suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.5 ml dose contains:

Active substance(s):

S. Enteritidis PT 4  $\geq 1$  RP\*

S. Typhimurium DT104  $\geq 1$  RP\*

\*See package leaflet

**3. PACKAGE SIZE**

250 ml (500 doses)

500 ml bottles (1000 doses)

**4. TARGET SPECIES**

Chickens (for reproduction and layer hen)

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Zero days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use immediately

## **9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Do not freeze.  
Protect from light.

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **13. NAME OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Ltd.

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 01708/5114

## **15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**Label – Low density polyethylene bottle (250 ml and 500 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis Salenvac T suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

250 ml (500 doses)  
500 ml (1000 doses)

Each 0.5 ml dose contains:

S. Enteritidis PT 4  $\geq 1$  RP\*

S. Typhimurium DT104  $\geq 1$  RP\*

\*See package leaflet

**3. TARGET SPECIES**

Chickens (for reproduction and layer hen)

**4. ROUTES OF ADMINISTRATION**

Intramuscular use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period: Zero days

**6. EXPIRY DATE**

Exp.{mm/yyyy}

Once broached use immediately.

**7. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

Keep the bottle in the outer carton.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Ltd.

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Nobilis Salenvac T suspension for injection for chickens

**2. Composition**

Each 0.5 ml dose contains:

**Active substances:**

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

Inactivated cells of *Salmonella* Typhimurium, strain DT104    ≥ 1RP\*

\* 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:**

Thiomersal                        0.065 mg

A homogeneous, cream to mid-brown suspension.

**3. Target species**

Chickens (for reproduction and layer hen).

**4. Indications for use**

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**

None.

## **6. Special warnings**

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.

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

Laying birds:

Do not use in birds in lay.

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.

Overdose:

Similar reactions to those seen after a single dose, but more pronounced after double dose.

Special restrictions for use and special conditions for use:

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## **7. Adverse events**

Chickens:

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

<sup>1</sup> 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. 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.

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

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

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

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

## **8. Dosage for each species, routes 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 periods**

Zero days

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.



Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription

### **14. Marketing authorisation numbers and pack sizes**

Vm 01708/5114

Pack sizes:

Cardboard box with one bottle of 250 ml (500 doses) and 500 ml (1000 doses).  
Not all pack sizes may be marketed.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder:

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

Manufacturer responsible for the batch release<sup>1</sup>:

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

Intervet International B.V.  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

Contact details to report suspected adverse reactions:  
MSD Animal Health UK Ltd.  
Tel.: +44 (0)1908 685685

## **17. Other information**

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.

POM-V Veterinary medicinal product subject to prescription

<sup>1</sup> The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

*Gavin Hall*  
Approved: 15 January 2025