LABELLING AND PACKAGE LEAFLET

A. LABELLING

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	≥ 1 RP*
S. Typhimurium DT104	≥ 1 RP*

*See package leaflet

3. PACKAGE SIZE

250 ml (500 doses)
500 ml (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 Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3044

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	≥ 1 RP*
S. Typhimurium DT104	≥ 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

9. BATCH NUMBER

Lot {number}

B. 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 *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

Excipient:
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 case of accidental self-injection, seek medical advice immediately and show the package leaflet or 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[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 cm^2) 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

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 01708/3044

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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch releaseand contact details to report suspected adverse reactions:

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

MSD Animal Health UK, Ltd., Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ
United Kingdom

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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.

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

Approved 05 November 2024
Gavin Hall