

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

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

Nobilis Salenvac ETC suspension for injection for chickens

**2. STATEMENT OF ACTIVE SUBSTANCES**

Per dose (0.5 ml):

S. Enteritidis, strain PT4, inac	1 - 6.6 RP*
S. Typhimurium, strain DT104, inac	1 - 16.1 RP
S. Infantis, strain A, S03499-06, inac	1 - 26.6 RP

\*RP (relative potency): Ratio of antigenic mass (in Units) as compared to the antigenic mass (in Units) of a reference batch which was shown to be efficacious in chickens.

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

500 ml (1000 doses)

**5. TARGET SPECIES**

Chickens (breeders and layers).

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP {month/year}

Once broached use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze.

Protect from light.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4613

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Low density polyethylene bottle (500 ml)

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

Nobilis Salenvac ETC suspension for injection for chickens

**2. STATEMENT OF ACTIVE SUBSTANCES**

Per dose (0.5 ml):

S. Enteritidis, strain PT4, inac	1 - 6.6 RP*
S. Typhimurium, strain DT104, inac	1 - 16.1 RP
S. Infantis, strain A, S03499-06, inac	1 - 26.6 RP

\*RP (relative potency): Ratio of antigenic mass (in Units) as compared to the antigenic mass (in Units) of a reference batch which was shown to be efficacious in chickens.

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

500 ml (1000 doses)

**5. TARGET SPECIES**

Chickens (breeders and layers).

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP {month/year}

Once broached use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze.

Protect from light.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4613

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Nobilis Salenvac ETC suspension for injection for chickens**

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

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

<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.

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

Nobilis Salenvac ETC suspension for injection for chickens

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

Each dose of 0.5 ml contains:

**Active substances:**

Inactivated <i>Salmonella</i> Enteritidis, strain PT4:	1 – 6.6 RP*
Inactivated <i>Salmonella</i> Typhimurium, strain DT104:	1 – 16.1 RP
Inactivated <i>Salmonella</i> Infantis, strain A, S03499-06:	1 – 26.6 RP

\*RP (relative potency): Ratio of antigenic mass (in Units) as compared to the antigenic mass (in Units) of a reference batch which was shown to be efficacious in chickens.

**Adjuvant:**

Aluminium hydroxide: 125 mg



**Excipients:**

Thiomersal: 0.065 mg

Suspension for injection.

A homogeneous, cream to mid-brown suspension.

**4. INDICATION(S)**

For the active immunisation of chickens from 6 weeks of age to reduce colonisation and faecal excretion of *S. Enteritidis* (serogroup D), *S. Typhimurium* and *S. Heidelberg* (serogroup B), *S. Infantis*, *S. Hadar* and *S. Virchow* (serogroup C).

Onset of immunity after the second vaccination

- *S. Enteritidis*, *S. Typhimurium*, *S. Infantis*, *S. Hadar* and *S. Virchow*: 4 weeks
- *S. Heidelberg*: 9 weeks\*

\*Earliest timepoint investigated

Duration of immunity after the second vaccination

- *S. Enteritidis*: 48 weeks (evidenced by challenge) and 90 weeks (evidenced by serology)
- *S. Typhimurium*: 57 weeks (evidenced by challenge) and 90 weeks (evidenced by serology)
- *S. Infantis*: 51 weeks (evidenced by challenge)
- *S. Hadar*: 51 weeks (evidenced by challenge)
- *S. Virchow*: 51 weeks (drawn from scientific reasoning)
- *S. Heidelberg*: 57 weeks (drawn from scientific reasoning)

**5. CONTRAINDICATIONS**

None.

**6. ADVERSE REACTIONS**

Vaccination may very commonly result in small (up to 8 mm in size) and transient palpable nodules at the injection site. These nodules completely disappear within 2 weeks after the second vaccination.

Vaccination may very commonly be associated with mild transient systemic effects such as reduced activity and food intake lasting up to 2 days after the first vaccination.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

**7. TARGET SPECIES**

Chickens (breeders and layers).

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Intramuscular injection of one dose of 0.5 ml from 6 weeks of age followed by a second vaccination with one dose of 0.5 ml at least 4 weeks later. The second vaccination should be administered no later than 3 weeks before the onset of lay.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Intramuscular use. Shake well before use. Syringes and needles must be sterile before use. Follow standard aseptic procedures.

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

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in a refrigerator (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 container: 10 hours.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

Not applicable.

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 insert or label to the physician.

Lay:

Do not use in birds in lay and within 3 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine 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 (symptoms, emergency procedures, antidotes):

No data available.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2020

**15. OTHER INFORMATION**

Pack size:

Cardboard box with 1 bottle of 500 ml (1000 doses).

Approved: 19/10/21

