

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/250 ml}**

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

Nobilis Erysipelas

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One dose (0.5 ml) contains:

Inactivated *Erysipelothrix rhusiopathiae*, strain M2 (serotype 2) ¼ RPU<sup>1</sup> / 0.5 ml dose. Adjuvanted with 37.5 mg/dose dl- $\alpha$ -tocopheryl acetate. Also contains 0.05% Formaldehyde as preservative.

<sup>1</sup> 1 RPU = 1 Relative Potency Unit, is the calculated potency compared to a reference serum obtained by means of a reference vaccine which has been tested and found to be satisfactory in pigs.

**3. PHARMACEUTICAL FORM**

Suspension for injection.

**4. PACKAGE SIZE**

1 x 250 ml (500 doses).

**5. TARGET SPECIES**

**6. INDICATION(S)**

For active immunisation of turkeys to reduce mortality caused by *Erysipelothrix rhusiopathiae*.

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

For subcutaneous administration.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

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

**10. EXPIRY DATE**

Expiry end of: {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. Shelf-life after first opening the immediate packaging: 10 hours. Keep the container in the outer carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

*[Distribution category]*

For animal treatment only.

To be supplied only on veterinary prescription.

POM-VPS

## **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**

MA Holder:

MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ

Distributor in Northern Ireland: Intervet Ireland Ltd. Magna Drive, Magna Business Park, Citywest Road, Dublin 24.

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

Vm 01708/4546

## **17. MANUFACTURER’S BATCH NUMBER**

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS {Label/250 ml}**

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

Nobilis Erysipelas  
Suspension for subcutaneous injection.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

One dose (0.5 ml) contains: Inactivated Erysipelothrix rhusiopathiae, strain M2 (serotype 2) ¼ RPU1 / 0.5 ml dose. Adjuvanted with 37.5 mg/dose dl- $\alpha$ -tocopheryl acetate. Also contains 0.05% Formaldehyde as preservative.

<sup>1</sup> 1 RPU = 1 Relative Potency Unit, is the calculated potency compared to a reference serum obtained by means of a reference vaccine which has been tested and found to be satisfactory in pigs.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

250 ml (500 doses).

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Batch: {number}

**7. EXPIRY DATE**

Expiry end of: {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

FOR ANIMAL TREATMENT ONLY. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. Shelf-life after first opening the immediate packaging: 10 hours Keep the container in the outer carton. Read package leaflet before use.

For active immunisation of turkeys to reduce mortality caused by *Erysipelothrix rhusiopathiae*.

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To be supplied only on veterinary prescription Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with the local requirements.

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Distributor in Northern Ireland: Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24. Vm 01708/4546

**PACKAGE LEAFLET FOR:**

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

MA holder

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

Manufacturer

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

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

Nobilis Erysipelas  
Suspension for injection.

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

**Active ingredient per 1 dose (0.5 ml)**

Inactivated *Erysipelothrix rhusiopathiae*, strain M2 (serotype 2) ¼ RPU<sup>1</sup> / 0.5 ml dose.

**Adjuvant:** dl α-tocopheryl acetate 37.5 mg dose.

**Preservative:** 0.05% Formaldehyde.

<sup>1</sup> 1 RPU = 1 Relative Potency Unit, is the calculated potency compared to a reference serum obtained by means of a reference vaccine which has been tested and found to be satisfactory in pigs.

**4. INDICATION(S)**

For active immunisation of turkeys to reduce mortality caused by *Erysipelothrix rhusiopathiae*.

Onset of Immunity: 6 weeks after second vaccination.

Duration of Immunity: 23 weeks after second vaccination.

## **5. CONTRAINDICATIONS**

Do not vaccinate laying birds or within 2 weeks before onset of the laying period.

## **6. ADVERSE REACTIONS**

None. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Turkeys.

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

**Dose:** 0.5 ml.

**Administration:** by subcutaneous injection.

Turkeys are to be vaccinated twice. Subcutaneous injection of 0.5 ml (one dose) of vaccine can take place from six weeks of age onwards. Vaccination is repeated after at least 4 weeks. The second vaccination for breeder turkeys has to be given not later than two weeks before the onset of the laying period.

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

Before using the vaccine allow it to reach room temperature (15-25°C) and shake before and intermittently during use. Use sterile syringes and needles.

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

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. Shelf-life after first opening the immediate packaging: 10 hours. Keep out of the sight and reach of children. Do not use after the expiry date, which is stated on the label and the carton.

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

### **Interaction**

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 decided on a case by case basis. Do not mix with any other veterinary medicinal product.

### **Special warnings for each target species**

Do not vaccinate unhealthy birds. A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

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

June 2020

### **15. OTHER INFORMATION**

For animal treatment only.

ATC Vet QI01CB02: Inactivated bacterial vaccines for Turkeys, Erysipelothrix vaccine The active ingredient is a cell lysate of *E. rhusiopathiae* strain M2 (serotype 2), which induces protection against turkey erysipelas.

### **PACK SIZES**

Carton with 1 glass bottle (type I Ph.Eur.) or PET bottles containing 250 ml (= 500 doses) or 500ml (= 1000 doses), closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap. Not all presentations may be marketed.

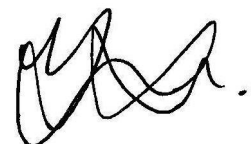
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Distributor in Northern Ireland

Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Road Dublin 24



Approved: 02 June 2020