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[1] / 0.5 ml dose. Adjuvanted with 37.5 mg/dose dl-α-tocopheryl acetate.
[1] 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

MSD Animal Health UK Ltd., 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-α-tocopheryl acetate.

[1] 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*.

POM-VPS

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.

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

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 Ltd.
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[1] / 0.5 ml dose.
Adjuvant: dl α-tocopheryl acetate 37.5 mg dose.

[1] 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. Avoid introduction of contamination by multiple broaching.

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
Vaccinate healthy animals only.

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

February 2021

15. OTHER INFORMATION

For animal treatment only.

Pharmacotherapeutic group: Inactivated bacterial vaccines for Turkeys

ATCvet code: QI01CB02:

The active ingredient is a cell lysate of E. rhusiopathiae strain M2 (serotype 2), which induces protection against turkey erysipelas.

PACK SIZES
Bottle of glass, hydrolytical class type I (Ph. Eur.) or PET-flask closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
1 bottle of 250 ml (500 doses) or 500 ml (1000 doses) packed in a cardboard box.
Not all pack sizes may be marketed.

POM-VPS

To be supplied only on veterinary prescription

Vm 01708/4546

Distributor in Northern Ireland

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

Approved: 04/03/21