

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Erysipelas

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active substance

Erysipelothrix rhusiopathiae, strain M2 (serotype 2) ¼ RPU*/ 0.5 ml dose

Adjuvant

dl α -tocopheryl acetate 37.5 mg/dose

Excipient

Preservative: Formaldehyde 0.05%

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target Species

Turkeys

4.2 Indications for use specifying the target species

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

The onset of immunity is 6 weeks post second vaccination and the duration of immunity is 23 weeks post second vaccination.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

Do not vaccinate unhealthy birds.

A good immune response is reliant on the reaction of an immunogenic agent

* 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.

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.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Dose: 0.5 ml

Administration: by subcutaneous injection

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.

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 4 weeks. The second vaccination for breeder turkeys has to be given not later than two weeks before the onset of the laying period.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No particular signs after administration of a double dose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
dl α -tocopheryl acetate
Polysorbate 80
Simethicone
Sodium chloride
Trometamol (Tris)
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Shelf-life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light

6.5 Nature and composition of immediate packaging

Carton with 1 glass bottle (type I Ph.Eur.) or PET bottle 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.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste material derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

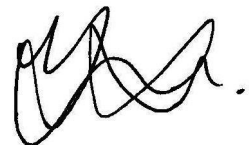
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9. DATE OF FIRST AUTHORISATION

26 September 2009

10. DATE OF REVISION OF THE TEXT

June 2020

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 02 June 2020