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

*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.

Adjuvant

dl α-tocopheryl acetate	37.5 mg/dose

Excipient

For the full list of excipients, see section 6.

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

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.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) 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

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.

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.

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

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major 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

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.

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4123

9. DATE OF FIRST AUTHORISATION

26 June 2009

10. DATE OF REVISION OF THE TEXT

September 2024

Gavin Hall

Approved: 03 January 2025