

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Erysipelas suspension for injection for turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) contains:

Active substances:

Erysipelothrix rhusiopathiae, strain M2 (serotype 2), inactivated: ³ 1 RPU*

* RPU = "relative potency unit" for turkeys, defined as 25% of 1 ppd "pig protective dose", determined by comparison with one in the potency test with pigs as effectively classified reference vaccine.

Adjuvant:

dl α -tocopheryl acetate 37.5 mg

Excipients:

| Qualitative composition of excipients and other constituents |
|---|
| Polysorbate 80 |
| Simethicone |
| Sodium chloride |
| Trometamol (Tris) |
| Hydrochloric acid |
| Water for injections |

Aqueous, white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Turkeys.

3.2 Indications for use for each target species

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

Onset of immunity: 6 weeks post second vaccination.

Duration of immunity: 23 weeks post second vaccination.

3.3 Contraindications

None.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Turkeys:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Do not use in birds in lay and within 2 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of 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 made on a case by case basis.

3.9 Administration routes and dosage

Dose: 0.5 ml.

Administration: Subcutaneous use.

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 must 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 °C - 25 °C) and shake before and intermittently during use. Use sterile syringes and needles. Avoid introduction of contamination by multiple broaching.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No particular clinical signs after administration of a two-fold overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01CB02.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

Pack sizes:

1 bottle of 250 ml (500 doses) or 500 ml (1 000 doses) packed in a cardboard box.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4123

8. DATE OF FIRST AUTHORISATION

26 June 2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 19 January 2026