

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:

Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11,
* IE_{50%} – Inhibition ELISA 50%.

> 3.34 log₂ IE_{50%}*

Adjuvants:

Aluminium hydroxide
DEAE-Dextran
Ginseng

5.29 mg (aluminium)

Excipients:

| Qualitative composition of excipients and other constituents |
|--|
| Disodium phosphate dodecahydrate |
| Potassium chloride |
| Potassium dihydrogen phosphate |
| Simethicone |
| Sodium chloride |
| Sodium hydroxide |
| Water for injections |

Whitish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

Onset of immunity: three weeks after completion of the basic vaccination scheme.

Duration of immunity: six months.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvants or to any of the excipients.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

| | |
|---|--|
| Very common (> 1 animal / 10 animals treated): | Injection site inflammation ¹ |
| Common (1 to 10 animals / 100 animals treated): | Elevated temperature ² |
| Very rare (< 1 animal / 10 000 animals treated, including isolated reports): | Anaphylactic-type reaction ³ |

¹Mild to moderate inflammation at the injection site that typically resolves within 4 days but in some cases may persist for up to 12 days post-vaccination.

²A transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours.

³An appropriate symptomatic treatment is recommended.

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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

Intramuscular use.

Allow the vaccine to reach room temperature (15 °C – 25 °C) before administration.
Shake well before use.

Administer one dose of 2 ml by intramuscular injection in the neck muscles according to the following schedule:

Basic vaccination:

Pigs from 6 months of age which have not been previously vaccinated with the product should be given two injections with an interval of 3 – 4 weeks. The second injection should be administered 3 – 4 weeks before mating.

Revaccination:

A single injection should be given 2 – 3 weeks prior to each subsequent mating (approximately every 6 months).

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

No adverse reactions other than those mentioned in section 3.6 were observed after the administration of a 2-fold vaccine dose.

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: QI09AB03.

To stimulate the development of active immunity in pigs against *E. rhusiopathiae*.

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: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Type I colourless glass vials of 20, 50 and 100 ml. The vials are closed with a rubber stopper and aluminium cap.

Polyethylene (PET) bottles of 20, 50, 100 and 250 ml.

Pack sizes:

Cardboard box with 1 glass vial of 10 doses (20 ml).

Cardboard box with 1 glass vial of 25 doses (50 ml).

Cardboard box with 1 glass vial of 50 doses (100 ml).

Cardboard box with 1 PET bottle of 10 doses (20 ml).

Cardboard box with 1 PET bottle of 25 doses (50 ml).

Cardboard box with 1 PET bottle of 50 doses (100 ml).

Cardboard box with 1 PET bottle of 125 doses (250 ml).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/166/001-007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 04/07/2014

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).