PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ERYSENG suspension for injection for pigs

2. Composition

Each dose of 2 ml contains:

Active substances:
Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, > 3.34 $\log_2$ $IE_{50\%}$ *
* $IE_{50\%}$ - Inhibition ELISA 50%.

Adjuvants:
Aluminium hydroxide 5.29 mg (aluminium)

Whitish suspension for injection.

3. Target species

Pigs.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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.

Overdose:
No adverse reactions other than already mentioned under section "Adverse events" can be expected after the administration of a 2-fold vaccine dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 (severe allergic reaction)[3]

[1]Mild 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.
[2]A transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours.
[3]An appropriate symptomatic treatment is recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular 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).

9. Advice on correct administration

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the cardboard box after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/14/166/001 - 007

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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona) SPAIN
TEL: +34 972 43 06 60

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representatives and contact details to report suspected adverse reactions:

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