1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG PARVO suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Inactivated porcine parvovirus, strain NADL-2, > 1.15 RP*
Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, > 3.34 $\log_2 IE_{50\%}$**
* RP – relative potency (ELISA).
** $IE_{50\%}$ – Inhibition ELISA 50 %.

Adjuvants:
Aluminium hydroxide 5.29 mg (aluminium)
DEAE-dextran
Ginseng

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 female pigs for the protection of progeny against transplacental infection caused by porcine parvovirus.
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:
Porcine parvovirus: from the beginning of the gestation period.
E. rhusiopathiae: three weeks after completion of the basic vaccination scheme.

Duration of immunity:
Porcine parvovirus: vaccination provides foetal protection for the duration of gestation.
Revaccination should be performed prior to each gestation, see section 3.9.
E. rhusiopathiae: vaccination protects against swine erysipelas until the time of the recommended revaccination (approximately six months after the basic vaccination scheme), see section 3.9.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances, 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]

[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 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

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with UNISTRAIN PRRS (where this vaccine is authorised) and administered at one injection site. The product information of UNISTRAIN PRRS should be consulted before administration of the mixed products.

The mixed administration of UNISTRAIN PRRS and ERYSENG PARVO should only be used when vaccinating animals prior to mating.

For mixed use, the onset and duration of immunity of the parvovirus component and the onset of immunity of the *Erysipelas* component have been demonstrated to be equivalent to those determined for ERYSENG PARVO when used alone. However, the duration of immunity of the *Erysipelas* component following mixed use has not been investigated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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

Allow the vaccine to reach room temperature (15 ºC – 25 ºC) 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).

For simultaneous use with UNISTRAIN PRRS in sows for reproduction from 6 months of age, the mixed administration of ERYSENG PARVO and UNISTRAIN PRRS should only be used when vaccinating animals prior to mating.

The following instructions should be used: the contents of a single vial of UNISTRAIN PRRS should be reconstituted with the contents of a single vial of ERYSENG PARVO. A single dose (2 ml) of the mixed vaccines should be injected within a period of 2 hours via intramuscular use.

UNISTRAIN PRRS		ERYSENG PARVO
10 doses	+	10 doses (20 ml)
25 doses	+	25 doses (50 ml)
50 doses	+	50 doses (100 ml)

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: QI09AL01.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with UNISTRAIN PRRS.

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.
Shelf life after mixing with UNISTRAIN PRRS: 2 hours.

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/2/14/167/001–007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/07/2014

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).