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, ... RP > 1.15 *
Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, ... ELISA > 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
Whitish suspension

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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 4.9.
E. rhusiopathiae: vaccination protects against swine erysipelas until the time of the recommended revaccination (approximately six months after the basic vaccination scheme), see section 4.9.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances, to the adjuvants or to any of the excipients.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

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

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:
- Mild to moderate inflammation at the injection site that typically resolves within four days but in some cases may persist for up to 12 days post-vaccination was observed in safety studies.

Common adverse reactions:
- A transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours was observed in safety studies.

Very rare adverse reactions:
- Anaphylactic-type reactions have been reported in spontaneous reports and appropriate symptomatic treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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)

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a 2-fold vaccine dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, Inactivated viral and bacterial vaccines.
ATCvet code: QI09AL01.

To stimulate active immunisation against porcine parvovirus and swine erysipelas.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE-dextran
Disodium phosphate dodecahydrate
Ginseng
Potassium chloride
Potassium dihydrogen phosphate
Simethicone
Sodium chloride
Sodium hydroxide
Water for injections

6.2 Major incompatibilities

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

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

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials 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 local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/167/001–007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/07/2014
Date of latest renewal:

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.