ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (20 ml, 50 ml, 100 ml, and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG PARVO suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

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 %.

3. PACKAGE SIZE

10 doses (20 ml)
25 doses (50 ml)
50 doses (100 ml)
125 doses (250 ml)

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated
Do not freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/14/167/001 10 doses
EU/2/14/167/002 25 doses
EU/2/14/167/003 50 doses
EU/2/14/167/004 10 doses
EU/2/14/167/005 25 doses
EU/2/14/167/006 50 doses
EU/2/14/167/007 125 doses

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottles (100 ml, 250 ml) and vials (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG PARVO suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

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 %.

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

50 doses (100 ml)
125 doses (250 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottles, (20 ml, 50 ml) and vials (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG PARVO

2. QUANTITATIVE PARTICULARS OF THE 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 %.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

5. PACKAGE SIZE

10 doses (20 ml)
25 doses (50 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ERYSENG PARVO suspension for injection for pigs

2. 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)

Whitish suspension for injection.

3. Target species

Pigs.

4. Indications for use

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, refer to section “Dosage for each species, route(s) and method of administration”.

E. rhusiopathiae: vaccination protects against swine erysipelas until the time of the recommended revaccination (approximately six months after the basic vaccination scheme), refer to section “Dosage for each species, route(s) and method of administration”.

5. Contraindications

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

Special precautions for the protection of the environment:
Not applicable.

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

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.

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 except with UNISTRAIN PRRS.

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

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)

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

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/2/14/167/001–007

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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