1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml (intramuscular use) or 0.2 ml (intradermal use) of reconstituted vaccine contains:

Active substance:
Porcine reproductive and respiratory syndrome virus, type 1, strain VP-046 BIS, live
$10^{3.5}$ - $10^{5.5}$ $CCID_{50}$
(*cell culture infectious dose*)

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatine
Povidone
Monosodium glutamate
Sodium chloride
Potassium chloride
Sucrose
Water for injections
Solvent (Phosphate buffer solution):
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

Lyophilisate: white to yellowish powder.
Solvent: Homogeneous-clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Breeding females: For active immunisation of breeding females from farms affected with European PRRS virus to reduce reproductive disorders, incidence and duration of viraemia, transplacental virus transmission, virus tissue load and clinical signs in the offspring associated with infection with strains of PRRS virus. Under laboratory conditions, vaccination of females reduced the negative impact of PRRS virus infection on piglet performance (mortality and weight gain) within the first 28 days of life.

Onset of immunity: 30 days after vaccination.

Duration of immunity: 16 weeks after vaccination.

Pigs from 3 weeks of age: For active immunisation of pigs from farms affected with European PRRS virus to reduce clinical signs associated with a PRRS virus infection, the incidence and duration of viraemia and the duration of virus shedding by infected animals. Under experimental conditions, it was demonstrated that vaccination reduces the virus tissue load in the lungs. Under field conditions, where a PRRSV infection occurred during the fattening period, a reduction in mortality and in the negative effects of infection on daily weight gain was demonstrated.

Onset of immunity: 28 days after vaccination.

Duration of immunity: 24 weeks after vaccination.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in naïve herds in which the presence of European PRRSV has not been established through reliable diagnostic virological methods.
No data are available on the safety of the vaccine for the reproductive performance in boars.

3.4 Special warnings

Vaccinate healthy animals only.
Precautions should be taken to avoid the transfer of the virus within the herd, e.g. from seropositive animals to seronegative animals.
Maternally derived antibodies can interfere with the efficacy of the vaccine. In the presence of high maternally derived antibodies, timing of initial vaccination of piglets should be planned accordingly.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccination should aim to achieve a homogenous immunity in the target population at farm level.
PRRS virus-naïve breeding animals (e.g. replacement gilts from PRRS virus-negative herds) which are introduced into a PRRSV-infected herd should be vaccinated prior to first insemination. Vaccination should preferably be done in a separated quarantine unit. A transition period should be respected between vaccination and moving the animals to the breeding unit. This transition period should be longer than the shedding phase of the PRRS MLV vaccine following vaccination.
Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.
In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time.

In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of the current vaccine following vaccination.

The vaccine virus may be shed after vaccination e.g. in the faeces and/or in nasal or oral secretions of vaccinated animals.
Following vaccination of breeding females the vaccine strain may be shed for up to nine days.
Following vaccination of 4 week old pigs, shedding of the vaccine strain may last for up to 29 days.
The vaccine strain can spread to non-vaccinated cohabitant animals, including the foetus during pregnancy and piglets after partum without any clinical consequence. Therefore, special precautions should be taken to avoid spreading to susceptible animals.

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):	Elevated temperature[1], Depression[2], Anorexia[2] Injection site inflammation[3], Injection site reddening[3]
Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[4], Injection site nodule[4]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction[5]

[1]Slight transient increases (not greater than 1.5 °C). These reactions spontaneously resolved without treatment.
[2]Mild and transient. These signs disappeared spontaneously without any additional treatment.
[3]After intradermal administration. Mild and transient, typically resolving within 2 days.
[4]After intramuscular administration. Mild and transient, typically resolving within one week.
[5]In such cases, an appropriate symptomatic treatment should be administered.

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

Breeding females:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with ERYSENG PARVO at one injection site by intramuscular route. The product literature of ERYSENG PARVO 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.

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

Pigs from 3 weeks of age:
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

For intramuscular or intradermal use:

- For the intramuscular route the vaccine should be given in the neck region.
- For the intradermal route:
    - in pigs from 3 weeks of age, the vaccine can be given in the neck region,
    - in breeding females, the vaccine can be given in the neck region, the perineal zone or the udder.

  The ID device supplied by the manufacturing authorisation holder or other suitable needle-free device able to administer 0.2 ml doses (injection stream diameter of 0.25 - 0.30 mm and a peak force of injection of 0.9 - 1.3 N) should be used.

  Aseptic injection techniques should be observed to avoid introduction of contamination during vaccine administration.

Reconstitute the vaccine with the corresponding solvent:

	Volume of solvent	
Nº of dose / vial	**IM**	**ID**
10 doses	20 ml	-
25 doses	50 ml	-
50 doses	100 ml	10 ml
100 doses	200 ml	20 ml
125 doses	250 ml	25 ml
250 doses	-	50 ml

If the solvent is refrigerated, it should be allowed to warm up to a temperature between 15 ºC to 25 ºC before reconstitution of the lyophilisate.

Peel the aluminium capsule off the bottle containing the solvent and aspirate in order to remove a certain volume of the contents. Then inject this volume of solvent into the vial containing the lyophilisate. Shake until the lyophilisate is completely dissolved. Once reconstituted, withdraw all the suspension obtained from the vaccine vial and inject it into the vial containing the remaining solvent. Shake well before use. The reconstituted vaccine is a homogeneous reddish solution. Avoid the

introduction of contamination during reconstitution and use. Use only sterile needles and syringes for administration.
The following doses and administration methods should be used:

Pigs from 3 weeks of age:
2 ml via intramuscular injection or 0.2 ml via intradermal administration.

Breeding females:
2 ml via intramuscular injection or 0.2 ml via intradermal administration. A single vaccination should be administered once in each reproductive cycle for protection during the subsequent pregnancy.

- In gilts, administer one injection of the reconstituted vaccine per animal 4 weeks before mating.
- In sows, administer one injection of the reconstituted vaccine per animal:
    - 2 weeks before each mating or
    - at 8 - 9 weeks of each gestation (approximately 60 days after mating) or
    - vaccinate sows every 4 months.

PRRS-naïve sows should not be vaccinated during pregnancy.

For simultaneous use with ERYSENG PARVO in breeding females from 6 months of age, the mixed administration of UNISTRAIN PRRS and ERYSENG PARVO 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 in the same way as described for reconstitution with solvent. 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)

Breeding females: Negative effects in the reproductive parameters could not be excluded following administration of a 10x overdose in naïve pregnant females, therefore PRRSV-naïve gilts or sows should not be vaccinated during pregnancy. Particular care and attention to the correct reconstitution of the vaccine and management of the vaccination procedure should be taken in order to avoid accidental overdose. Special precautions should be taken to avoid overdose in naïve pregnant females.

No adverse reactions were observed in seropositive gilts and sows or in their offspring following the administration of a 10x overdose during the 2nd or 3rd trimester of gestation. However, viremia in piglets may be uncommonly observed in seropositive sows vaccinated with a 10x overdose during the 3rd trimester of pregnancy.

Pigs from 3 weeks of age: No adverse reactions were observed in naïve piglets following administration of a 10x overdose other than those mentioned in section 3.6.

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.

The import, sale, supply and/or use of UNISTRAIN PRRS is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03.

To stimulate active immunity against virulent European PRRS virus (type I) in pigs and breeding females.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale in glass containers: 5 years.
Shelf life of the solvent as packaged for sale in PET containers: 3 years.
Shelf life after reconstitution with solvent: within 4 hours.
Shelf life after mixing with ERYSENG PARVO: 2 hours.

5.3 Special precautions for storage

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

Solvent:
Store below 25 °C.
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Solvent: Colourless Type I glass vial (10 and 20 ml), Type II glass vial (50, 100 and 250 ml) or PET vials (10, 20, 50, 100 and 250 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Package sizes:
Cardboard box for intramuscular use:
1 vial with 10 doses of lyophilisate and 1 vial with 20 ml of solvent.

1 vial with 25 doses of lyophilisate and 1 vial with 50 ml of solvent.
1 vial with 50 doses of lyophilisate and 1 vial with 100 ml of solvent.
1 vial with 100 doses of lyophilisate and 1 vial with 200 ml of solvent.
1 vial with 125 doses of lyophilisate and 1 vial with 250 ml of solvent.
10 vials with 10, 25, 50, 100 or 125 doses of lyophilisate.
10 vials with 20, 50, 100, 200 or 250 ml of solvent.

Cardboard box for intradermal use:
1 vial with 50 doses of lyophilisate and 1 vial with 10 ml of solvent.
1 vial with 100 doses of lyophilisate and 1 vial with 20 ml of solvent.
1 vial with 125 doses of lyophilisate and 1 vial with 25 ml of solvent.
1 vial with 250 doses of lyophilisate and 1 vial with 50 ml of solvent.
10 vials with 50, 100, 125 or 250 doses of lyophilisate.
10 vials with 10, 20, 25 or 50 ml of solvent.

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)

VPA10846/013/001

8. DATE OF FIRST AUTHORISATION

01/03/2013

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

25/06/2025

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).