

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAN 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
 $10^{3.5} - 10^{5.5}$ CCID₅₀

(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 4 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

¹Slight transient increases (not greater than 1.5 °C). These reactions spontaneously resolved without treatment.

²Mild and transient. These signs disappeared spontaneously without any additional treatment.

³After intradermal administration. , Mild and transient, typically resolving within 2 days.

⁴After intramuscular administration. Mild and transient, typically resolving within one week.

⁵In 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 4 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:
 - o in pigs from 4 weeks of age, the vaccine can be given in the neck region,
 - o 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:

N° of dose / vial	Volume of solvent	
	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 °C to 25 °C 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 4 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:
 - o 2 weeks before each mating or
 - o at 8 - 9 weeks of each gestation (approximately 60 days after mating) or
 - o 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 4 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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 vial (10 doses) of lyophilisate and 1 vial (20 ml) of solvent.
1 vial (25 doses) of lyophilisate and 1 vial (50 ml) of solvent.
1 vial (50 doses) of lyophilisate and 1 vial (100 ml) of solvent.
1 vial (100 doses) of lyophilisate and 1 vial (200 ml) of solvent.
1 vial (125 doses) of lyophilisate and 1 vial (250 ml) of solvent.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Lyophilisate:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. PACKAGE SIZE

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

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 reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Keep the bottles in the outer carton in order to 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
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 vial (50 doses) of lyophilisate and 1 vial (10 ml) of solvent.
1 vial (100 doses) of lyophilisate and 1 vial (20 ml) of solvent.
1 vial (125 doses) of lyophilisate and 1 vial (25 ml) of solvent.
1 vial (250 doses) of lyophilisate and 1 vial (50 ml) of solvent.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.2 ml) contains:

Lyophilisate:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. PACKAGE SIZE

1 vial (50 doses) of lyophilisate and 1 vial (10 ml) of solvent.
1 vial (100 doses) of lyophilisate and 1 vial (20 ml) of solvent.
1 vial (125 doses) of lyophilisate and 1 vial (25 ml) of solvent.
1 vial (250 doses) of lyophilisate and 1 vial (50 ml) of solvent.

4. TARGET SPECIES

Pigs.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Keep the bottles in the outer carton in order to 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
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials (10, 25, 50, 100 and 125 doses) of lyophilisate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRRAIN PRRS lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. PACKAGE SIZE

10 vials of 10 doses.

10 vials of 25 doses.

10 vials of 50 doses.

10 vials of 100 doses.

10 vials of 125 doses.

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 reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Keep the bottles in the outer carton in order to 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
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials (50, 100 125 and 250 doses) of lyophilisate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRRAIN PRRS lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.2 ml) contains:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. PACKAGE SIZE

10 vials of 50 doses.

10 vials of 100 doses.

10 vials of 125 doses.

10 vials of 250 doses.

4. TARGET SPECIES

Pigs.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Keep the bottles in the outer carton in order to 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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials (20, 50, 100, 200 and 250 ml) of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS solvent

2. STATEMENT OF ACTIVE SUBSTANCES**3. PACKAGE SIZE**

10 vials of 20 ml.
10 vials of 50 ml.
10 vials of 100 ml.
10 vials of 200 ml.
10 vials of 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}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Do not freeze.

Keep the bottles in the outer carton in order to 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
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials (10, 20, 25 and 50 ml) of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS solvent

2. STATEMENT OF ACTIVE SUBSTANCES**3. PACKAGE SIZE**

10 vials of 10 ml.

10 vials of 20 ml.

10 vials of 25 ml.

10 vials of 50 ml.

4. TARGET SPECIES

Pigs.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Do not freeze.

Keep the bottles in the outer carton in order to 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
--

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 vial (10, 25, 50, 100 and 125 doses) of lyophilisate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (2 ml) contains:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 doses.

25 doses.

50 doses.

100 doses.

125 doses.

6. ROUTES OF ADMINISTRATION

Intramuscular use.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 vial (50, 100, 125 and 250 doses) of lyophilisate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAN PRRS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (0.2 ml) contains:

PRRSV-type 1, strain VP-046 BIS, live

$10^{3.5} - 10^{5.5}$ CCID₅₀

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 4 hours.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses.

100 doses.

125 doses.

250 doses.

6. ROUTES OF ADMINISTRATION

Intradermal use.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 vial (20 and 50 ml) of solvent.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISTRAIN PRRS solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**3. BATCH NUMBER**

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml.

50 ml.

6. ROUTES OF ADMINISTRATION

Intramuscular use.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

1 vial (100, 200 and 250 ml) of solvent.

1. NAME OF THE DILUENT

UNISTRAIN PRRS solvent

2. TARGET SPECIES

Pigs.

3. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

4. EXPIRY DATE

Exp. {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Do not freeze.

Keep the bottles in the outer carton in order to protect from light.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. BATCH NUMBER

Lot {number}

8. PACKAGE SIZE

100 ml

200 ml

250 ml

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

1 vial (10, 20, 25 and 50 ml) of solvent.

1. NAME OF THE DILUENT

UNISTRAIN PRRS solvent

2. TARGET SPECIES

Pigs.

3. ROUTE(S) OF ADMINISTRATION

Intradermal use.

4. EXPIRY DATE

Exp. {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Do not freeze.

Keep the bottles in the outer carton in order to protect from light.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. BATCH NUMBER

Lot {number}

8. PACKAGE SIZE

10 ml

20 ml

25 ml

50 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

UNISTRAIN PRRS lyophilisate and solvent for suspension for injection for pigs

2. Composition

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

Active substance:

PRRSV-type 1, strain VP-046 BIS, live
(cell culture infectious dose)

$10^{3.5} - 10^{5.5}$ CCID₅₀

Lyophilisate: white to yellowish powder.

Solvent: Homogeneous-clear solution.

3. Target species

Pigs.

4. Indications for use

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 4 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 the 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.

5. Contraindications

Do not use in cases of hypersensitivity to the active ingredient 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.

6. Special warnings

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.

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 fetus 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.

Pregnancy and lactation:

Can be used during pregnancy and lactation (see section “Overdose”).

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 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.

Pigs from 4 weeks of age:

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:

Breeding females: Negative effects in the reproductive parameters could not be excluded following the 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 4 weeks of age: No adverse reactions were observed in naïve piglets after an overdose administration (10 doses).

Special restrictions for use and special conditions for use:

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.

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 "Interaction with other medicinal products and other forms of interaction"

7. 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

¹Slight transient increases (not greater than 1.5 °C). These reactions spontaneously resolved without treatment.

²Mild and transient. These signs disappeared spontaneously without any additional treatment.

³After intradermal administration. Mild and transient, typically resolving within 2 days.

⁴After intramuscular. Mild and transient, typically resolving within one week.

⁵In such cases, an appropriate symptomatic treatment should be administered.

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

For intramuscular or intradermal use:

- For the intramuscular route the vaccine should be given in the neck region.
- For the intradermal route:
 - o in pigs from 4 weeks of age, the vaccine can be given in the neck region,
 - o 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.

The following doses and administration methods should be used:

Pigs from 4 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:
 - o 2 weeks before each mating or
 - o at 8 - 9 weeks of each gestation (approximately 60 days after mating) or
 - o vaccinate sows every 4 months

PRRS-naïve sows should not be vaccinated during pregnancy.

9. Advice on correct administration

Reconstitute the vaccine with the corresponding solvent:

N° of dose/ vial	Volume of solvent	
	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 °C to 25 °C 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.

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)

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: within 4 hours.
Shelf life after mixing with ERYSENG PARVO: 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> how to dispose of medicines no longer required.

13. 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: [To be completed nationally].

Pack 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.

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 \(https://medicines.health.europa.eu/veterinary\)](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

Local representatives and contact details to report suspected adverse reactions:

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

[To be completed nationally].

17. Other information