Summary of Product Characteristics

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 contains:

Freeze-dried powder:
Active substance:
Live attenuated Porcine reproductive and respiratory syndrome virus (PRRSV), strain VP-046 BIS
..... $10^{3.5}$– $10^{5.5}$ $CCID_{50}$
(*cell culture infectious dose*)

Solvent:
Phosphate buffer solution.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

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

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in case 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate healthy animals only.
For an optimal control of PRRS virus, it is advised to mass vaccinate all target pigs within a herd from the earliest recommended age onwards. Newly introduced PRRSV-naïve females (e.g. replacement females from PRRSV-negative herds) should be vaccinated prior to pregnancy.
The vaccine virus may be shed after vaccination e.g. in the faecesa 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, if necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case adverse reactions develop following accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Slight transient increases (not greater than 1.5°C) in body temperature following vaccination occurred very commonly in studies. These reactions spontaneously resolved without treatment.
Mild and transient depression or anorexia following vaccination occurred very commonly in studies. These signs disappeared spontaneously without any additional treatment.

After intradermal administration, local reactions (inflammation and/or redness) following vaccination occurred very commonly in studies. These local reactions were mild and transient, typically resolving within 2 days.

After intramuscular administration injection site reactions (small nodules and/or inflammation) following vaccination occurred commonly in studies. The lesions were mild and transient, typically resolving within one week.

Vaccination very rarely caused hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be administered.

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.
The safety of the vaccine, when administered beyond 60 days of pregnancy, has not been studied.

4.8 Interaction with other medicinal products and other forms of interactions

Breeding females:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with ERYSENG PARVO and administered 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. 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

The method of administration is by intramuscular or by intradermal route.

For both the intramuscular and intradermal routes, the vaccine should be given in the neck region. For the intradermal route, the ID device supplied by the manufacturing authorisation holder or other suitable needle-free device able to administer 0.2 ml doses (force of injection spring: 400-190N; stream nozzle diameter: 0.25mm) should be used.

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

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 freeze-dried powder. Shake until the freeze-dried powder 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 administrated 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 mating or at 8-9 weeks of gestation (approximately 60 days after mating).

In each gestation, vaccinate the females according to the above-mentioned schedules.
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)

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

Breeding females: Negative effects in the reproductive parameters could not be excluded following administration of a 10x overdose in naïve pregnant females. 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.

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 4.6.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines, Porcine Reproductive and Respiratory Syndrome (PRRS) virus vaccine.
ATCvet code: QI09AD03.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Freeze-dried powder:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatine
Povidone
Monosodium glutamate
Sodium chloride
Potassium chloride
Sucrose
Water for injections

Solvent:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with the solvent supplied with the product or with ERYSENG PARVO.

6.3 Shelf-life

Shelf life of the freeze-dried powder 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.

6.4 Special precautions for storage

Freeze-dried powder: Store and transport refrigerated (2° C - 8° C). Do not freeze. Protect from light.
Solvent: Store and transport below +25°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Freeze-dried powder: 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:
Intramuscular use:
Cardboard box containing 1 vial with 10 doses of freeze-dried powder and 1 vial with 20 ml of solvent.
Cardboard box containing 1 vial with 25 doses of freeze-dried powder and 1 vial with 50 ml of solvent.
Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 100 ml of solvent.
Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 200 ml of solvent.
Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 250 ml of solvent.
Cardboard box containing 10 vials with 10, 25, 50, 100 or 125 doses of freeze-dried powder.
Cardboard box containing 10 vials with 20, 50, 100, 200 or 250 ml of solvent.

Intradermal use:
Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 10 ml of solvent.
Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 20 ml of solvent.
Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 25 ml of solvent.
Cardboard box containing 10 vials with 50, 100 or 125 doses of freeze-dried powder.
Cardboard box containing 10 vials with 10, 20 or 25 ml of solvent.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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)

VPA10846/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2013
Date of last renewal: 15th September 2017

10 DATE OF REVISION OF THE TEXT

January 2020

PROHIBITION OF SALE, SUPPLY AND/OR 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.