ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Inactivated *Bordetella bronchiseptica,* strain 833CER: 9.8 BbCC(*)
Recombinant Type D *Pasteurella multocida* toxin (PMTr): ≥ 1 MED_{63}(**)

(*) *Bordetella bronchiseptica* Cell Count in log_{10}.
(**) Murine Effective Dose 63: vaccination of mice with 0.2 ml of a 5-fold diluted vaccine by subcutaneous route induces seroconversion in at least 63% of the animals.

Adjuvants:
Aluminium hydroxide gel 6.4 mg (aluminium)
DEAE-Dextran
Ginseng

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde	0.8 mg
Simethicone	
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Sodium chloride	
Potassium chloride	
Water for injections	

White homogeneous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

For the passive protection of piglets via colostrum after active immunisation of sows and gilts to reduce the clinical signs and lesions of progressive and non-progressive atrophic rhinitis, as well as to reduce weight loss associated with *Bordetella bronchiseptica* and *Pasteurella multocida* infections during the fattening period.

Challenge studies have demonstrated that passive immunity lasts until piglets are 6 weeks of age while in clinical field trials, the beneficial effects of vaccination (reduction in nasal lesion score and weight loss) are observed until slaughter.

3.3 Contraindications

Do not use in case 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:

Not applicable.

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

In case of accidental self-injection only a minor injection site reaction is expected.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows and gilts):

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1] Elevated temperature[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction)[3]

[1]After the administration of one dose of vaccine a swelling of less than 2 to 3 cm in diameter can occur at the injection site which may last up to five days and occasionally up to two weeks.
[2]An increase in body temperature of about 0.7 °C can occur during the first 6 hours after injection. An increase of rectal temperature up to 1.5º C may occur. This rectal temperature increase is spontaneously resolved within 24 hours without treatment.
[3]An appropriate symptomatic treatment should be administered without delay.

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:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

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

Intramuscular use.

Allow the vaccine to reach room temperature (15 ˚C - 25 ˚C) 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: sows and gilts which have not been previously vaccinated with the product should be given two injections with an interval of 3-4 weeks. The first injection should be administered 6-8 weeks before the expected date of farrowing.

Revaccination: a single injection should be given 3-4 weeks prior to each subsequent farrowing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions other than already mentioned under point 3.6 can be expected, except for an increase of rectal temperature up to 2 ºC. This rectal temperature increase is spontaneously resolved within 24 hours without treatment.

Discoloration of muscular fibres of the inoculation site (0.5 cm wide x 2 cm long) may be observed at necropsy in 10% of animals. This discoloration is attributable to aluminium hydroxide and may be observed up to seven weeks after the injection of a double dose of vaccine.

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: QI09AB04

To stimulate active immunity in order to provide passive immunity to the progeny against atrophic rhinitis associated with *Bordetella bronchiseptica* and *Pasteurella multocida* infections.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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: 10 hours stored at room temperature.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I colourless glass vials of 20 ml.
Type II colourless glass vials of 50 ml and 100 ml .

The vials are closed with a rubber stopper and aluminium cap.

20 ml, 50 ml, 100 ml and 250 ml polyethylene (PET) bottles closed with a rubber stopper and aluminium cap.

Pack sizes:
- Cardboard box with 1 or 10 glass vials of 10 doses.
- Cardboard box with 1 glass vial of 25 doses.
- Cardboard box with 1 glass vial of 50 doses.

- Cardboard box with 1 or 10 PET bottles of 10 doses.
- Cardboard box with 1 PET bottle of 25 doses.
- Cardboard box with 1 PET bottle of 50 doses.
- Cardboard box with 1 PET bottle of 125 doses.

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/2/10/109/001-009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 16/09/2010

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (2 ml):
Inactivated *Bordetella bronchiseptica,* strain 833CER: 9.8 BbCC
Recombinant Type D *Pasteurella multocida* toxin (PMTr): ≥ 1 MED_{63}

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs (sows and gilts).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within a 10-hour period, stored at 15 ºC to 25 ºC.

9. SPECIAL STORAGE PRECAUTIONS

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

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/2/10/109/001 (1 glass vial 20 ml)
EU/2/10/109/002 (10 glass vials 20 ml)
EU/2/10/109/003 (1 glass vial 50 ml)
EU/2/10/109/004 (1 glass vial 100 ml)
EU/2/10/109/005 (1 PET bottle 20 ml)
EU/2/10/109/006 (10 PET bottles 20 ml)
EU/2/10/109/007 (1 PET bottle 50 ml)
EU/2/10/109/008 (1 PET bottle 100 ml)
EU/2/10/109/009 (1 PET bottle 250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE AND VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (2 ml):

Inactivated *Bordetella bronchiseptica,* strain 833CER:	9.8 BbCC
Recombinant Type D *Pasteurella multocida* toxin (PMTr):	≥ 1 MED_{63}

3. TARGET SPECIES

Pigs (sows and gilts).

4. ROUTES OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within a 10-hour period, stored at 15 ºC to 25 ºC.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose (2 ml):
Inactivated *Bordetella bronchiseptica,* strain 833CER: 9.8 BbCC
Recombinant Type D *Pasteurella multocida* toxin (PMTr): ≥ 1 MED_{63}

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within a 10-hour period, stored at 15 ºC to 25 ºC.

5. PACKAGE SIZE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RHINISENG suspension for injection for pigs

2. Composition

Each dose of 2 ml contains:

Active substances:

Inactivated *Bordetella bronchiseptica,* strain 833CER:	9.8 BbCC(*)
Recombinant Type D *Pasteurella multocida* toxin (PMTr):	≥ 1 MED_{63}(**)

(*) *Bordetella bronchiseptica* Cell Count in log_{10}.
(**) Murine Effective Dose 63: vaccination of mice with 0.2 ml of a 5-fold diluted vaccine by subcutaneous route induces seroconversion in at least 63 % of the animals.

Adjuvants:

Aluminium hydroxide gel	6.4 mg (aluminium)

Excipient:

Formaldehyde	0.8 mg

White homogeneous suspension.

3. Target species

Pigs (sows and gilts).

4. Indications for use

For passive protection of piglets via colostrum after active immunisation of sows and gilts to reduce the clinical signs and lesions of progressive and non-progressive atrophic rhinitis, as well as to reduce weight loss associated with *Bordetella bronchiseptica* and *Pasteurella multocida* infections during the fattening period.

Challenge studies have demonstrated that passive immunity lasts until piglets are 6 weeks of age while in clinical field trials, the beneficial effects of vaccination (reduction in nasal lesion score and weight loss) are observed until slaughter.

5. Contraindications

Do not use in case 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:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection only a minor injection site reaction is expected.

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

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose:
No adverse reactions other than already mentioned under point "Adverse reactions" can be expected, except for an increase of rectal temperature up to 2 ºC. This rectal temperature increase is spontaneously resolved within 24 hours without treatment.

Discoloration of muscular fibres of the inoculation site (0.5 cm wide x 2 cm long) may be observed at necropsy in 10% of animals. This discoloration is attributable to aluminium hydroxide and may be observed up to seven weeks after the injection of a double dose of vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs (sows and gilts):

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1] Elevated temperature[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction)[3]

[1]After the administration of one dose of vaccine a swelling of less than 2 to 3 cm in diameter can occur at the injection site which may last up to five days and occasionally up to two weeks.
[2]An increase in body temperature of about 0.7°C can occur during the first 6 hours after injection. An increase of rectal temperature up to 1.5ºC may occur. This rectal temperature increase is spontaneously resolved within 24 hours without treatment.
[3]An appropriate symptomatic treatment should be administered without delay.

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

Intramuscular use.

Administer one dose of 2 ml by intramuscular injection in the neck muscles according to the following schedule:

Basic vaccination: sows and gilts which have not been previously vaccinated with the product should be given two injections with an interval of 3-4 weeks. The first injection should be administered 6-8 weeks before the expected date of farrowing.

Revaccination: a single injection should be given 3-4 weeks prior to each subsequent farrowing.

9. Advice on correct administration

Allow the vaccine to reach room temperature (15 ˚C - 25 ˚C) 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 °C - 8 °C).
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours stored at 15 ºC to 25 ºC.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/10/109/001-009

Pack sizes:
- Cardboard box with 1 or 10 glass vials of 10 doses.
- Cardboard box with 1 glass vial of 25 doses.
- Cardboard box with 1 glass vial of 50 doses.

- Cardboard box with 1 or 10 PET bottles of 10 doses.
- Cardboard box with 1 PET bottle of 25 doses.
- Cardboard box with 1 PET bottle of 50 doses.
- Cardboard box with 1 PET bottle of 125 doses.

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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