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

Excipient:
Formaldehyde..... 0.8 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances, to the adjuvants or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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.

4.6 Adverse reactions (frequency and seriousness)

Common adverse reactions:

- Transient local reactions may occur after the administration of one dose of vaccine. A transient slight 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.

- A transient 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.

Very rare adverse reactions:

- Anaphylactic type reactions have been reported in spontaneous reports and appropriate symptomatic treatment is recommended.

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.

4.8 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.

4.9 Amounts to be administered and administration route

Intramuscular use.

Allow the vaccine to reach room temperature (15-25˚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.

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

No adverse reactions other than already mentioned under point 4.6 can be expected, except for an increase of rectal temperature up to 2ºC. 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines (Bordetella and Pasteurella) for pigs.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE-dextran
Ginseng
Formaldehyde
Simethicone
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.

6.3 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.

6.4. Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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
Tel. +34 972 430660
Fax. +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/109/001-009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16/09/2010

Date of last renewal: 30/06/2015

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

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.

ANNEX II

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances

Laboratorios Hipra, S.A.
Avda la Selva, 135
17170 Amer (Girona)
Spain

Laboratorios Hipra, S.A.
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
17170 Amer (Girona)
Spain

Name and address of the manufacturer<s> responsible for batch release

Laboratorios Hipra, S.A.
Avda la Selva, 135
17170 Amer (Girona)
Spain

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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. PHARMACEUTICAL FORM

Suspension for injection.

4. 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 (20ml)
10 x 10 doses (20 ml)
1 x 25 doses (50 ml)
1 x 50 doses (100 ml)

5. TARGET SPECIES

Pigs (sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/109/001-009

17. MANUFACTURER'S BATCH NUMBER

Batch {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. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (sows and gilts).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/109/004
EU/2/10/109/008
EU/2/10/109/009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG suspension for injection for pigs.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

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

4. ROUTE(S) OF ADMINISTRATION

IM.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/ year}
Once opened, use within a 10-hour period, stored at 15 ºC to 25 ºC.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
RHINISENG suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHINISENG suspension for injection for pigs.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Excipient:
Formaldehyde..... 0.8 mg

White homogeneous suspension.

4. INDICATION(S)

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. ADVERSE REACTIONS

Common adverse reactions:

- Transient local reactions may occur after the administration of one dose of vaccine. A transient slight 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.

- A transient 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.

Very rare adverse reactions:

- Anaphylactic type reactions have been reported in spontaneous reports and appropriate symptomatic treatment is recommended.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows and gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 (15-25˚C) before administration.

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C to 8 °C).
Protect from light.
Do not freeze.
Do not use after the expiry date stated on the label.
Shelf life after first opening the immediate packaging: 10 hours stored at 15 ºC to 25 ºC.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Only healthy animals should be vaccinated.

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.

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 (symptoms, emergency procedures, antidotes):
No adverse reactions other than already mentioned under point "Adverse reactions" can be expected, except for an increase of rectal temperature up to 2ºC. 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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

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

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Česká republika HIPRA SLOVENSKO, s.r.o. Tel. (421) 02 32 335 223	**Magyarország** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
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Κύπρος LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**Sverige** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
Latvija LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**United Kingdom** HIPRA UK AND IRELAND, Ltd. Tel. (+44) 0115 845 6486