ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, ... ELISA > 3.34 $\log_2$ $IE_{50\%}$*
* $IE_{50\%}$ – Inhibition ELISA 50%.

Adjuvants:
Aluminium hydroxide .....5.29 mg (aluminium)
DEAE-Dextran
Ginseng.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Whitish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

Onset of immunity: three weeks after completion of the basic vaccination scheme.
Duration of immunity: six months.

4.3 Contraindications

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

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals

None.

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.

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:
- Mild to moderate inflammation at the injection site that typically resolves within four days but in some cases may persist for up to 12 days post-vaccination was observed in safety studies.

Common adverse reactions:
- A transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours was observed in safety studies.

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 and lactation.

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 ºC) 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:
Pigs from 6 months of age which have not been previously vaccinated with the product should be given two injections with an interval of 3–4 weeks. The second injection should be administered 3–4 weeks before mating.

Revaccination:
A single injection should be given 2–3 weeks prior to each subsequent mating (approximately every 6 months).

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a 2-fold vaccine dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, Inactivated bacterial vaccines, *erysipelothrix*.
ATCvet code: QI09AB03.

To stimulate active immunisation against swine erysipelas.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE-dextran
Disodium phosphate dodecahydrate
Ginseng
Potassium chloride
Potassium dihydrogen phosphate
Simethicone
Sodium chloride
Sodium hydroxide
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: use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC).

Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I colourless glass vials of 20, 50 and 100 ml. The vials are closed with a rubber stopper and aluminium cap.

Polyethylene (PET) bottles of 20, 50, 100 and 250 ml.

Pack sizes:
Cardboard box with 1 glass vial of 10 doses (20 ml).
Cardboard box with 1 glass vial of 25 doses (50 ml).

Cardboard box with 1 glass vial of 50 doses (100 ml).

Cardboard box with 1 PET bottle of 10 doses (20 ml).
Cardboard box with 1 PET bottle of 25 doses (50 ml).
Cardboard box with 1 PET bottle of 50 doses (100 ml).
Cardboard box with 1 PET bottle of 125 doses (250 ml).

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/166/001-007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4/07/2014
Date of latest renewal:

10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturers of the biological active substance

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 (Gerona)
SPAIN

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance 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 AND THE IMMEDIATE PACKAGE

Cardboard box, (20 ml, 50 ml, 100ml, and 250ml)
bottles (100 ml and 250 ml) and vials (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, ... ELISA > 3.34 $\log_2 IE_{50\ \%}$*
* $IE_{50\%}$ – Inhibition ELISA 50%.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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/2/14/166/001
EU/2/14/166/002
EU/2/14/166/003
EU/2/14/166/004
EU/2/14/166/005
EU/2/14/166/006
EU/2/14/166/007

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottles (20 ml, 50 ml) and vials (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYSENG suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11, ... ELISA > 3.34 $\log_2$ $IE_{50\,\%}$*
* $IE_{50\%}$ – Inhibition ELISA 50%.

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

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
ERYSENG 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

ERYSENG suspension for injection for pigs

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

Each does of 2 ml contains:

Inactivated *Erysipelothrix rhusiopathiae,* strain R32E11, ... ELISA > 3.34 $\log_2$ $IE_{50\%}$ *
* $IE_{50\%}$ - Inhibition ELISA 50%.

Aluminium hydroxide .....5.29 mg (aluminium)
DEAE-Dextran
Ginseng.

Whitish suspension for injection.

4. INDICATION(S)

For the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

Onset of immunity: three weeks after completion of the basic vaccination scheme.
Duration of immunity: six months.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Very common adverse reactions:
- Mild to moderate inflammation at the injection site that typically resolves within four days but in some cases may persist for up to 12 days post-vaccination was observed in safety studies.

Common adverse reactions:
- A transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours was observed in safety studies.

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.

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:
Pigs from 6 months of age which have not been previously vaccinated with the product should be given two injections with an interval of 3–4 weeks. The second injection should be administered 3–4 weeks before mating.

Revaccination:
A single injection should be given 2–3 weeks prior to each subsequent mating (approximately every 6 months).

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach room temperature (15–25 ºC) 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 ºC – 8 ºC).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate only healthy animals.

Special precautions for use in animals:
None.
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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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 section “Adverse reactions” can be expected after the administration of a 2-fold vaccine dose.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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 glass vial of 10 doses (20 ml).
Cardboard box with 1 glass vial of 25 doses (50 ml).
Cardboard box with 1 glass vial of 50 doses (100 ml).

Cardboard box with 1 PET bottle of 10 doses (20 ml).
Cardboard box with 1 PET bottle of 25 doses (50 ml).
Cardboard box with 1 PET bottle of 50 doses (100 ml).
Cardboard box with 1 PET bottle of 125 doses (250 ml).

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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France HIPRA FRANCE Tél. (+33) 02 51 80 77 91	**Portugal** ARBUSET, Produtos Farmacêuticos e Sanitários De Uso Animal, Lda Tel. (+351) 219 663 450
Hrvatska LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**România** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
Ireland LABORATORIOS HIPRA, S.A. Tel: (34) 972 43 06 60	**Slovenija** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
Ísland LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**Slovenská republika** HIPRA SLOVENSKO, s.r.o. Tel. (421) 02 32 335 223

Italia Hipra Italia S.r.l. Tel. (+39) 030 7241821	**Suomi/Finland** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
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	