ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Recombinant verotoxin 2e of *E. coli* ..... RP* ≥ 1.50
* RP – relative potency (ELISA)

Adjuvants:
Aluminium hydroxide (Al^{3+}) ..... 2.117 mg
DEAE-dextran ..... 10 mg.

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

Active immunisation of piglets from 2 days of age to prevent mortality and reduce clinical signs of oedema disease (caused by verotoxin 2e produced by *E. coli*) and to reduce the loss of daily weight gain during the finishing period in the face of infections with verotoxin 2e producing *E. coli* until slaughter from 164 days of age.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 112 days after vaccination.

4.3 Contraindications

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

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:

- Mild inflammation at the injection site (< 5 cm in diameter) that typically resolves within three days post-vaccination without treatment.
- Mild depression during the day of vaccination.
- Temperature rise of maximum 1.1 °C was observed. Temperatures returned to normal within 24 hrs.

Emesis, recumbency, convulsion, lethargy and loss of consciousness occur in very rare cases within a few minutes after vaccination. The animals mostly start to recover within around 15 minutes. In case of severe anaphylactic-type reactions appropriate 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
The use is not recommended 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 a single intramuscular injection of 1 ml in the neck muscles.

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

No information is available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia).
ATC vet code: QI09AB02.

The vaccine consisting of recombinant verotoxin 2e stimulates an active immunity against VT2e toxin produced by the causative agent of oedema disease in pigs. Vaccinated animals are able to neutralise the VT2e toxin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE-dextran
Simethicone
Sodium hydroxide
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium 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: 36 months.
Shelf life after first opening the immediate packaging: 10 hours.

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

Polyethylene (PET) vials of 10, 50, 100 and 250 ml.
The vials are closed with a bromobutyl rubber stopper and aluminium cap.

Cardboard box with 1 vial of 10 doses (10 ml).
Cardboard box with 10 vials of 10 doses (10 ml).
Cardboard box with 1 vial of 50 doses (50 ml).
Cardboard box with 1 vial of 100 doses (100 ml).
Cardboard box with 1 vial of 250 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/2/17/214/001–005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17/08/2017

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

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER 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.
C-63 Km 48.3 de Polígon el Rieral
17170 Amer (Girona)
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.

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 with vial of 10 x10 doses.
Cardboard box with vials of 10, 50, 100 or 250 doses.
Vial of 100 or 250 doses.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED suspension for injection for pigs
recombinant verotoxin 2e of *E. coli*

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
Recombinant verotoxin 2e of *E. coli*..... RP ≥ 1.50.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 doses (10 ml)
50 doses (50 ml)
100 doses (100 ml)
250 doses (250 ml)
10 x 10 doses (10 ml)

5. TARGET SPECIES

Pigs.

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

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

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/2/17/214/001 (10 doses (10 ml))
EU/2/17/214/002 (50 doses (50 ml))
EU/2/17/214/003 (100 doses (100 ml))
EU/2/17/214/004 (250 doses (250 ml))
EU/2/17/214/005 (10 x 10 doses (10 ml))

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 10 or 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Recombinant verotoxin 2e of *E. coli*..... RP ≥ 1.50 per ml.

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

10 doses (10 ml)
50 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 within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
VEPURED 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

VEPURED suspension for injection for pigs

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

Each dose of 1 ml contains:

Active substance:
Recombinant verotoxin 2e of *E. coli*..... RP* ≥ 1.50
*RP – relative potency (ELISA)

Adjuvants:
Aluminium hydroxide ..... 2.117 mg (aluminium)
DEAE-dextran

Whitish suspension for injection.

4. INDICATION(S)

Active immunisation of piglets from 2 days of age to prevent mortality and reduce clinical signs of oedema disease (caused by verotoxin 2e produced by *E. coli*) and to reduce the loss of daily weight gain during the finishing period in the face of infections with verotoxin 2e producing *E. coli* until slaughter from 164 days of age.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 112 days after vaccination.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Very common adverse reactions:
- Mild inflammation at the injection site (< 5 cm in diameter) that typically resolves within three days post-vaccination without treatment.
- Mild depression during the day of vaccination.

- Temperature rise of maximum 1.1 °C was observed. Temperatures returned to normal within 24 hrs.

Emesis, recumbency, convulsion, lethargy and loss of consciousness occur in very rare cases within a few minutes after vaccination. The animals mostly start to recover within around 15 minutes. In case of severe anaphylactic-type reactions appropriate 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 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 a single intramuscular injection of 1 ml in the neck muscles.

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: 10 hours.

12. SPECIAL WARNING(S)

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
The use is not recommended 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.

Major 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 polyethylene (PET) vial of 10 doses (10 ml).
Cardboard box with 10 PET vials of 10 doses (10 ml).
Cardboard box with 1 PET vial of 50 doses (50 ml).
Cardboard box with 1 PET vial of 100 doses (100 ml).
Cardboard box with 1 PET vial of 250 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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