

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 (Al₃₊)

2.117 mg

DEAE-dextran

10 mg.

Excipients:

Qualitative composition of excipients and other constituents
Simethicone
Sodium hydroxide
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Whitish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each 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: 3 weeks after vaccination.

Duration of immunity: 16 weeks after vaccination.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvant 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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very common (> 1 animal / 10 animals treated):	Injection site inflammation ¹ Depression ² , Elevated temperature ³
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. emesis, recumbency, convulsion, lethargy and loss of consciousness) ⁴

¹Mild inflammation at the injection site (< 5 cm in diameter) that typically resolves within three days post-vaccination without treatment.

²Mild depression during the day of vaccination.

³Temperature rise of maximum 1.1 °C was observed. Temperatures returned to normal within 24 hrs.

⁴ Hypersensitivity reactions may occur 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.

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

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.

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 a single intramuscular injection of 1 ml in the neck muscles.

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

No information is available.

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: 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.

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: 3 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

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

5.4 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.

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/2/17/214/001–005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17/08/2017

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 \(https://medicines.health.europa.eu/veterinary\)](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 with vial of 10 x 10 doses****Cardboard box with vials of 10, 50, 100 or 250 doses****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VEPURED suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Recombinant verotoxin 2e of *E. coli*RP $\geq$ 1.50.**3. PACKAGE SIZE**

10 doses (10 ml)

50 doses (50 ml)

100 doses (100 ml)

250 doses (250 ml)

10 x 10 doses (10 ml)

4. TARGET SPECIES

Pigs.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

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
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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))

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 or 250 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Recombinant verotoxin 2e of *E. Coli*

RP $\geq$ 1.50.

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES
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100 doses (100 ml)

250 doses (250 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 10 or 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Recombinant verotoxin 2e of *E. coli*

RP $\geq$ 1.50 per ml.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

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

10 doses (10 ml)

50 doses (50 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VEPURED suspension for injection for pigs

2. 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

2.117 mg (aluminium)

DEAE-dextran

10 mg

Whitish suspension for injection.

3. Target species

Pigs.

4. Indications for use

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: 3 weeks after vaccination.

Duration of immunity: 16 weeks 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. Special warnings

Special warnings:

Vaccinate healthy animals only.

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.

7. Adverse events

Pigs:

Very common (> 1 animal / 10 animals treated):
Injection site inflammation ¹ Depression ² , Elevated temperature ³
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Hypersensitivity reaction (e.g. emesis, recumbency, convulsion, lethargy and loss of consciousness) ⁴

¹Mild inflammation at the injection site (< 5 cm in diameter) that typically resolves within three days post-vaccination without treatment.

²Mild depression during the day of vaccination.

³Temperature rise of maximum 1.1 °C was observed. Temperatures returned to normal within 24 hrs.

⁴ Hypersensitivity reactions may occur 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.

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 a single intramuscular injection of 1 ml in the neck muscles.

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).

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. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 10 hours.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/17/214/001–005

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.

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 \(https://medicines.health.europa.eu/veterinary\)](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:

België/Belgique/Belgien

HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Lietuva

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ISPANIJA
Tel: +34 972 43 06 60

Република България

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ИСПАНИЯ
Тел: +34 972 43 06 60

Luxembourg/Luxemburg

HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Česká republika

HIPRA SLOVENSKO, s.r.o.
Zochova 5,
811 03 Bratislava,
SLOVENSKO
Tel: +421 02 32 335 223

Magyarország

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANYOLORSZÁG
Tel: +34 972 43 06 60

Danmark

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIEN
Tel: +34 972 43 06 60

Malta

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANJA
Tel: +34 972 43 06 60

Deutschland

HIPRA DEUTSCHLAND GmbH
Am Wehrhahn 28-30
40211 Düsseldorf
DEUTSCHLAND
Tel: +49 211 698236 – 0

Nederland

HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Eesti

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
HISPAANIA
Tel: +34 972 43 06 60

Ελλάδα

HIPRA ΕΛΛΑΣ Α.Ε.
Λεωφ. Αθηνών 80 & Μηριόνου 2-4,
104 41 Κολωνός - ΑΘΗΝΑ - ΕΛΛΑΣ
Τηλ: +30 210 4978660

España

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ESPAÑA
Tel: +34 972 43 06 60

France

HIPRA FRANCE
7 rue Roland Garros, Batiment H
44700 - Orvault -
FRANCE
Tél: +33 02 51 80 77 91

Hrvatska

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ŠPANJOLSKA
Tel: +34 972 43 06 60

Ireland

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPAIN
Tel: +34 972 43 06 60

Ísland

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPÁNN
Sími: +34 972 43 06 60

Italia

Hipra Italia S.r.l.
Enrico Mattei, 2
25030 Coccaglio (BS)
ITALIA
Tel: +39 030 7241821

Norge

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIA
Tlf: +34 972 43 06 60

Österreich

HIPRA DEUTSCHLAND GmbH
Am Wehrhahn 28-30
40211 Düsseldorf
DEUTSCHLAND
Tel: +49 211 698236 – 0

Polska

HIPRA POLSKA Sp.z.o.o.
Ul. Wincentego Rzymowskiego 31
02-697 Warszawa - POLSKA
Tel: +48 22 642 33 06

Portugal

ARBUSET, Produtos Farmacêuticos e Sanitários
De Uso Animal, Lda
Portela de Mafra e Fontainha - Abrunheira
2665 – 191 Malveira - PORTUGAL
Tel: +351 219 663 450

România

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIA
Tel: +34 972 43 06 60

Slovenija

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ŠPANIIJA
Tel: +34 972 43 06 60

Slovenská republika

HIPRA SLOVENSKO, s.r.o.
Zochova 5,
811 03 Bratislava,
SLOVENSKO
Tel: +421 02 32 335 223

Suomi/Finland

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ESPANJA
Puh/Tel: +34 972 43 06 60

Κύπρος

LABORATORIOS HIPRA, S.A.

Avda. La Selva 135

17170 Amer (Girona)

ΙΣΠΑΝΙΑ

Τηλ: +34 972 43 06 60

Sverige

LABORATORIOS HIPRA, S.A.

Avda. La Selva 135

17170 Amer (Girona)

SPANIEN

Tel. +34 972 43 06 60

Latvija

LABORATORIOS HIPRA, S.A.

Avda. La Selva 135

17170 Amer (Girona)

SPĀNIJA

Tel. +34 972 43 06 60

United Kingdom (Northern Ireland)

LABORATORIOS HIPRA, S.A.

Avda. La Selva 135

17170 Amer (Girona)

SPAIN

Tel: +34 972 43 06 60