ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Active substance:
Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strainV-1037
≥ 70 % cELISA40*
(*) ≥ 70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

Adjuvant:
Mineral oil 104.125 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0,05 mg
Sorbitan mono-oleate	
Polysorbate 80	
Sodium chloride	
Potassium chloride	
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Water for injections	

Whitish emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Rabbits

3.2 Indications for use for each target species

For active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2).

Onset of immunity: 1 week.
Duration of immunity: 1 year demonstrated by challenge

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

The vaccine provides protection only against RHDV2, cross protection against classical RHDV has not been demonstrated.
Vaccination is recommended where RHDV2 is epidemiologically relevant.Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Pregnant does should be handled with special care to avoid stress and risk of abortion.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Rabbits:

Very common (> 1 animal / 10 animals treated):	Elevated temperature[1] Injection site nodule[2], Injection site swelling[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Lethargy[3], Inappetence[3]

[1]A transient temperature slightly above 40 ºC, between 2 or 3 days following vaccination that resolves spontaneously without treatment by day 5 post vaccination.
[2]Local reactions (< 2 cm) that may last 24 hours and gradually reduce and disappear without need for treatment.
[3]May be observed in the first 48 hours after injection.

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:
Laboratory studies in doe rabbits in the last third of gestation have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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

Subcutaneous use.
Administer 1 dose (0.5 ml) of the vaccine to rabbits from the age of 30 days by subcutaneous injection in the lateral thoracic wall.

Revaccination: 1 year after the last vaccination.

Before use allow the vaccine to reach room temperature.
Shake well before administration.

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

No available data.

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: QI08AA01

To stimulate active immunity against the rabbit haemorrhagic disease type 2 virus (RHDV2).
Vaccination of rabbits induced the production of hemagglutination inhibition antibodies that persisted for at least 1 year.

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: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Keep the vial(s) in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type I colourless glass vials with 0.5 ml (1 dose), 5 ml (10 doses) and 20 ml (40 doses).
High-density polyethylene (HDPE) vials with 100 ml (200 doses).
The vials are closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box of 10 glass vials of 1 dose (0.5 ml)
Cardboard box of 1 glass vial of 10 doses (5 ml)
Cardboard box of 1 glass vial of 40 doses (20 ml)
Cardboard box of 1 HDPE vial of 200 doses (100 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/2/16/199/001 (5 ml)
EU/2/16/199/002 (20 ml)
EU/2/16/199/003 (0.5 ml)
EU/2/16/199/004 (100 ml)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 22 September 2016

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

CABOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.5 ml contains:
Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strain V-1037 ≥ 70 %
cELISA40*
(*) ≥ 70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

3. PACKAGE SIZE

10 x 1 dose (0.5 ml)
1 x 10 doses (5 ml)
1 x 40 doses (20 ml)
1 x 200 doses (100 ml)

4. TARGET SPECIES

Rabbits

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the vial(s) in the outer carton in order to 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

EU/2/16/199/001 (5 ml)
EU/2/16/199/002 (20 ml)
EU/2/16/199/003 (0.5 ml)
EU/2/16/199/004 (100 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 200 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.5 ml contains:
Inactivated RHDV2, strain V-1037: ≥ 70 % cELISA40*
(*) ≥ 70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

3. TARGET SPECIES

Rabbits

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the vial(s) in the outer carton in order to protect from light

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

10 PACKAGE SIZE

1 x 200 doses (100 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL OF 1, 10, or 40 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 0.5 ml contains:
Inactivated RHDV2, strain V-1037: ≥ 70 % cELISA40*
(*)≥ 70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

5. PACKAGE SIZE

10 x 1 dose (0.5 ml)
1 x 10 doses (5 ml)
1 x 40 doses (20 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ERAVAC emulsion for injection for rabbits

2. Composition

Each dose of 0.5 ml contains:

Active substance:
Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strain V-1037: ≥ 70 % cELISA40*
(*) ≥ 70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

Adjuvant:
Mineral oil: 104.125 mg

Excipients:
Thiomersal: 0.05 mg

Whitish emulsion.

3. Target species

Rabbits.

4. Indications for use

For active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2).

Onset of immunity: 1 week
Duration of immunity: 1 year demonstrated by challenge

5. Contraindications

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

6. Special warnings

Special warnings:
The vaccine provides protection only against RHDV2, cross protection against classical RHDV has not been demonstrated.
Vaccination is recommended where RHDV2 is epidemiologically relevant.
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Pregnant does should be handled with special care to avoid stress and risk of abortion.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:
Laboratory studies in doe rabbits in the last third of gestation have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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:
Not applicable

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

7. Adverse events

Rabbits:

Very common (> 1 animal / 10 animals treated):
Elevated temperature[1] Injection site nodule[2], Injection site swelling[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Lethargy[3], Inappetence[3]

[1]A transient temperature slightly above 40 ºC, between 2 or 3 days following vaccination that resolves spontaneously without treatment by day 5 post vaccination.
[2]Local reactions (< 2 cm) that may last 24 hours and gradually reduce and disappear without need for treatment.
[3]May be observed in the first 48 hours after injection.

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

Subcutaneous use.

Administer 1 dose (0.5 ml) of the vaccine to rabbits from the age of 30 days by subcutaneous injection in the lateral thoracic wall.
Revaccination: 1 year after the last vaccination.

9. Advice on correct administration

Before use allow the vaccine to reach room temperature.
Shake well before administration.

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.
Keep the vial(s) in the outer carton in order to 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 immediate packaging: use immediately.

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 Authorization numbers:
EU/2/16/199/001 (5 ml)
EU/2/16/199/002 (20 ml)
EU/2/16/199/003 (0.5 ml)
EU/2/16/199/004 (100 ml)

Pack sizes:
Cardboard box of 10 glass vial of 1 dose (0.5 ml)
Cardboard box of 1 glass vial of 10 doses (5 ml)
Cardboard box of 1 glass vial of 40 doses (20 ml)
Cardboard box of 1 HDPE vial of 200 doses (100 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).

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

Local representatives and contact details to report suspected adverse reactions:

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

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