ANNEX II

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

Name and address of the manufacturer of the biological active substance

Laboratorios Hipra, S.A.
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
17170 Amer
SPAIN

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. La Selva, 135
17170 Amer
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 are 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

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits.

2. STATEMENT OF ACTIVE SUBSTANCES

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. PHARMACEUTICAL FORM

Emulsion for injection.

4. 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)

5. TARGET SPECIES

Rabbits

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Shake well before administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read the 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)

Vm 17533/5000

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label (1, 10, 40 or 200 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAVAC emulsion for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated RHDV2, strain V-1037: …….≥70% cELISA40
≥70 % of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

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

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. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch{number}

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:

ERAVAC emulsion for injection for rabbits

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

ERAVAC
Emulsion for injection for rabbits.

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

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.

4. INDICATION(S)

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: 12 months 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. ADVERSE REACTIONS

A transient temperature increase slightly above 40 ºC between two or three days following vaccination was observed very commonly during safety studies. This slight temperature increase resolves spontaneously without treatment by day 5 post vaccination.

Nodules or swellings (< 2 cm) at the injection site were observed very commonly during safety studies. These local reactions may last 24 hours and gradually reduce and disappear without need for treatment.

Lethargy and/or inappetence in the first 48 hours after injection may be observed very rarely , based on post-authorisation pharmacovigilance reporting.

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

Rabbits.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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: every 12 months after the last vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

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

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 – 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.
Shelf life after first opening the immediate packaging: Use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The vaccine provides protection only against RHDV2, cross protection against classical RHDV has not been demonstrated.
Vaccinate healthy animals only.

Special precautions for use in animals:
Vaccination is recommended where RHDV2 is epidemiologically relevant.

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

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 available data.

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 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

15. OTHER INFORMATION

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.

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

United Kingdom (Northern Ireland)
LABORATORIOS HIPRA, S.A.
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Approved: 16 September 2021