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:
Thiomersal……0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Whitish emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits

4.2 Indications for use, specifying the 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: 12 months demonstrated by challenge

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

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 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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 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.

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

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

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.

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

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

No available data.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for Leporidae, inactivated viral vaccine for rabbits, rabbit haemorrhagic disease virus.
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 12 months.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil
Thiomersal
Sorbitan mono-oleate
Polysorbate 80
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
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.
Keep the vial(s) in the outer carton in order to protect from light.

6.5 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.

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

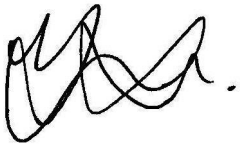
Vm 17533/5000

9. DATE OF FIRST AUTHORISATION

22 September 2016

10. DATE OF REVISION OF THE TEXT

September 2021



Approved: 16 September 2021