

ERAVAC

Emulsion for injection for rabbits

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

STATEMENT OF THE ACTIVE SUBSTANCE(S):

Each dose of 0.5 ml contains:

Active substance:

Inactivated rabbit haemorrhagic disease type 2 virus (RHDV2), strain V-1037: $\geq 70\%$ cELISA40*

(* $\geq 70\%$ of vaccinated rabbits shall give cELISA antibody titres equal to or higher than 40.

Whitish emulsion.

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: 9 months demonstrated by challenge.

CONTRAINDICATIONS:

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

ADVERSE REACTIONS:

Very common: a transient temperature increase slightly above 40 °C might occur between two or three days following vaccination. This slight temperature increase resolves spontaneously without treatment by day 5 post-vaccination.

Very common: nodules or swelling (< 2 cm) can be observed in the injection site, which may last 24 hours. These local reactions gradually reduce and disappear without need for treatment.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reactions).

- 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.

TARGET SPECIES: Rabbits.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION:

Subcutaneous use.

Administer 1 dose (0.5 ml) of the veterinary medicinal product to rabbits from the age of 30 days by subcutaneous injection in the lateral thoracic wall.

Revaccination: 9 months after vaccination.

ADVICE ON CORRECT ADMINISTRATION:

Before use allow the vaccine to reach room temperature.

Shake well before administration.

WITHDRAWAL PERIOD(S):

Zero days.

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.

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

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 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.

Pregnancy

Laboratory studies in pregnant doe rabbits in the last third of gestation have not produced any evidence of a teratogenic, foetotoxic and 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 products.

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

03/01/2018

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

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).

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.

For Animal Treatment Only.



LABORATORIOS HIPRA, S.A. Avda. la Selva, 135 . 17170 Amer (Girona) Spain

Tel. (34) 972 43 06 60. Fax (34) 972 43 06 61. hipra@hipra.com