SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

YURVAC RHD emulsion for injection for rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substance:
Recombinant RHDV2 virus capsid protein RP*≥ 0.7
*Relative potency (ELISA test)

Adjuvant:
Light 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
Polysorbate 80	0.03 g
Sorbitan mono-oleate	
Sodium chloride	
Potassium chloride	
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Water for injections	

White homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Rabbits, including pet (dwarf) rabbits.

3.2 Indications for use for each target species

For active immunisation of rabbits from 30 days of age onwards to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains.
For passive immunisation against RHDV2 in kits born to does vaccinated between 9 and 2 months before parturition, shown by challenge at 30 days of age.

Onset of immunity:	7 days for RHDV2 14 days for RHDV
Duration of immunity:	1 year

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Pregnant does should be handled gently to avoid stress and risk of abortion.
No safety study on the reproductive performance has been conducted in male rabbits (bucks).

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.

Other precautions

Not applicable.

3.6 Adverse events

Rabbits, including pet (dwarf) rabbits:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site inflammation[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anorexia[3] Intestinal stasis[3] Lethargy[3] Lameness[3]

[1] The highest individual rectal temperature increase was 1.52 ºC which returned to normal values 24 hours later.
[2] Inflammation (< 2 cm) at the injection can be observed. These local reactions gradually reduce and disappear within 7 days without need for treatment.
[3] Transient.

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 and lactation:

Can be used 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

Subcutaneous use.

Primary vaccination:
Administer one dose (0.5 ml) subcutaneously to rabbits from 30 days of age onwards.

Revaccination:
Revaccinate annually with one dose (0.5 ml) by subcutaneous injection.

Allow the vaccine to reach room temperature before use.

Shake well before administration.

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

No adverse reactions other than those mentioned in section 3.6 were observed after the administration of a 5-fold dose.

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 period(s)

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

ATCvet code: QI08AV.

The vaccine is intended to stimulate active immunity against RHDV and RHDV2.
The active substance of the vaccine is the recombinant RHDV2 capsid protein, which auto-assembles into virus like particles (VLPs).

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: 1 year.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I colourless glass vials with 0.5 ml (1 dose) or 5 ml (10 doses).
The vials are closed with a rubber stopper and an aluminium cap.

Type I colourless polyethylene terephthalate (PET) vials with 20 ml (40 doses) or 100 ml (200 doses).
The vials are closed with a rubber stopper and an 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 PET vial of 40 doses (20 ml).
Cardboard box of 1 PET vial of 200 doses (100 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA

7. MARKETING AUTHORISATION NUMBER

Vm 17533/5020

8. DATE OF FIRST AUTHORISATION

26 September 2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 16 February 2026