

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD BOX)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

YURVAC RHD emulsion for injection for rabbits

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.5 ml dose contains:

Recombinant RHDV2 virus capsid protein                      RP\* $\geq$  0.7

\* Relative potency (ELISA test)

**3. PACKAGE SIZE**

10 x 1 dose (0.5 ml).

10 doses (5 ml).

40 doses (20 ml).

200 doses (100 ml).

**4. TARGET SPECIES**

Rabbits, including pet (dwarf) rabbits.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous route.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 10 hours.

## **9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Keep the vial 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 SA

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 17533/5020

## **15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (VIAL OF  
200 DOSES)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

YURVAC RHD emulsion for injection for rabbits

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.5 ml dose contains:

Recombinant RHDV2 virus capsid protein                      RP\* $\geq$  0.7

\* Relative potency (ELISA test)

**3. TARGET SPECIES**

Rabbits, including pet (dwarf) rabbits.

**4. ROUTES OF ADMINISTRATION**

Subcutaneous use.

Read the package leaflet before use.

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

200 doses.

**6. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**7. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 10 hours.

## **8. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

## **9. NAME OF THE MARKETING AUTHORISATION HOLDER**

Laboratorios Hipra SA

## **10. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (VIAL OF 1 DOSE, 10 DOSES AND 40 DOSES)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

YURVAC RHD emulsion for injection for rabbits

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each 0.5 ml dose contains:

Recombinant RHDV2 virus capsid protein                      RP\* $\geq$  0.7

\* Relative potency (ELISA test)

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 10 hours.

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 dose

10 doses

40 doses

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

YURVAC RHD emulsion for injection for rabbits

**2. Composition**

Each 0.5 ml dose contains:

**Active substance:** Recombinant RHDV2 virus capsid protein      RP\* $\geq$  0.7

\* Relative potency (ELISA test)

**Adjuvant:** Light mineral oil      104.125 mg

White homogeneous emulsion.

**3. Target species**

Rabbits, including pet (dwarf) rabbits.

**4. Indications for use**

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

**5. Contraindications**

None.

## **6. Special warnings**

### Special warnings:

Vaccinate healthy animals only.

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.

### Pregnancy and lactation:

Can be used during pregnancy and lactation.

Pregnant does should be handled gently 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:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

**7. Adverse events**

Rabbits, including pet (dwarf) rabbits:

Very common (> 1 animal / 10 animals treated):	Elevated temperature <sup>1</sup> Injection site inflammation <sup>2</sup>
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<sup>1</sup> The highest individual rectal temperature increase was 1.52 °C which returned to normal values 24 hours later.

<sup>2</sup> Inflammation (< 2 cm) at the injection can be observed. These local reactions gradually reduce and disappear within 7 days without need for treatment.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

**8. Dosage for each species, routes and method of administration**

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.



## **9. Advice on correct administration**

Allow the vaccine to reach room temperature before use.

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 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 container: 10 hours.

## **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**

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.

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#### **15. PID link (Do not print heading)**

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Laboratorios Hipra SA  
Avda La Selva 135  
17170 Amer (Girona)  
Spain  
Tel. +34 972 43 06 60

#### **17. Other information**

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*Gavin Hall*

Approved: 26 September 2024