YURVAC® RHD

Emulsion for injection for rabbits

Name of the veterinary medicinal product
YURVAC RHD emulsion for injection for rabbits.
Composition
Each dose of 0.5 ml contains:
Active substance:
Recombinant RHDV2 virus capsid protein RP*≥ 0.7
* Relative Potency (ELISA test)
White homogeneous emulsion.
Target species
Rabbits, including pet (dwarf) rabbits.
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.
Onset of immunity: 7 days for RHDV2. 14 days for RHDV.
Duration of immunity: 1 year.
Contraindications
Do not use in cases of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.
Special warnings
Special warnings:
Vaccinate healthy animals only.
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.
Pregnancy and lactation:
Can be used during pregnancy and lactation.
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.
Special restrictions for use and special conditions for use:
Not applicable.
Major incompatibilities:
Do not mix with any other veterinary medicinal product.
Adverse events
Rabbits, including pet (dwarf) rabbits:

Very common (> 1 animal / 10 animals treated):	Elevated temperature[1] Injection site inflammation[2]

[1] The highest individual rectal temperature increase was 1.15 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 without need for treatment.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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.
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.
Advice on correct administration
Allow the vaccine to reach room temperature before use.
Shake well before use.
Withdrawal periods
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.
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 and the carton.
Shelf life after first opening the immediate packaging: 10 hours.
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.
Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.
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.
Date on which the package leaflet was last revised
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).
Contact details
Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona) SPAIN
Tel. +34 972 43 06 60
Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona) SPAIN
Tel: +34 972 43 06 60

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