13 September 2024
EMA/CVMP/433078/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

YURVAC RHD

Common name: Rabbit haemorrhagic disease and RHDV2 vaccine (recombinant)

On 12 september 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product YURVAC RHD. The marketing authorisation holder for this veterinary medicinal product is Laboratorios Hipra, S.A.

YURVAC RHD is currently authorised as emulsion for injection 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

The variation concerns the introduction of a new indication and to include a required pharmacovigilance text under annex II. Based on the efficacy data provided in a study performed on the offspring of does vaccinated with this vaccine, the new indication is as follows:

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

For passive immunisation against RHDV2 (not demonstrated against highly virulent strains) of the offspring of the vaccinated does for at least 30 days.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.