14 July 2023
EMA/CVMP/311987/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

YURVAC RHD

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

On 11-13 July 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product YURVAC RHD emulsion for injection for rabbits. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

YURVAC RHD is an immunological containing recombinant rabbit haemorrhagic disease virus (RHDV2) virus capsid protein (ATCvet code QI08AV) as active substance. After administration, the vaccine induces active immunisation of rabbits, including pet (dwarf) rabbits.

The benefits of YURVAC RHD are an 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.

The most common side effects are elevated temperature (the highest individual rectal temperature increase was 1.15 ºC which returned to normal values 24 hours later) and injection site inflammation (< 2 cm that gradually reduces and disappears without need for treatment).

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

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for YURVAC RHD and therefore recommends the granting of the marketing authorisation.

[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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