EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 June 2021
EMA/CVMP/306191/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Fatrovax RHD

Common name: Rabbit haemorrhagic disease vaccine (inactivated, recombinant)

On 17 June 2021, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Fatrovax RHD suspension for injection, intended for rabbits and pet (dwarf) rabbits. The applicant for this veterinary medicinal product is Fatro S.p.A.

Fatrovax RHD is an immunological veterinary medicinal product containing rabbit haemorrhagic disease virus 1 (RHDV1) recombinant capsid protein VP1a and rabbit haemorrhagic disease virus 2 (RHDV2) recombinant capsid protein VP1ab as active substances (ATCvet code: QI08AA01). Fatrovax RHD acts by stimulating active immunity against RHDV1 and RHDV2.

The benefits of Fatrovax RHD are the reduction of mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2, which causes high mortality rates in young and adult rabbits; increase in the range of available treatment possibilities for RHD for a minor species; and obtaining the active substances by means of biotechnology, avoiding the use of rabbits in the production of the vaccine. The most common side effect is formation of a very small transient nodule at the site of injection, which may commonly be visible or palpable in the first week post vaccination. The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application for marketing authorisation.

The full indication is: For active immunisation of rabbits from the age of 28 days to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2.
Onset of immunity: 1 week (7 days) after vaccination
Duration of immunity: 1 year

Detailed conditions for the use of this product are described in the summary of product characteristics

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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(SPC) which will be published in the European public assessment report (EPAR) 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 Fatrovax RHD and therefore recommends the granting of the marketing authorisation.