5 December 2019
EMA/CVMP/640568/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion (post-authorisation)

Eravac

Common name: rabbit haemorrhagic disease vaccine (inactivated)

On 5 December 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[1] recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Eravac. The marketing authorisation holder for this veterinary medicinal product is Laboratorios Hipra, S.A.

Eravac is an emulsion for injection for active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2). The variation concerns the extension in the duration of immunity from 9 months to 12 months and the update of section 4.6 of the SPC following the last PSUR.

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 revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] 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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