21 June 2024
EMA/CVMP/252070/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Divence IBR Marker Live

Common name: Bovine herpesvirus type 1 (live) vaccine.

On 19 June 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Divence IBR Marker Live, lyophilisate and solvent for emulsion for injection, intended for cattle. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Divence IBR Marker Live is a live vaccine containing bovine herpesvirus type 1 (BoHV-1), strain CEDDEL, gE- tk- double-gene deleted (ATCvet code QI02AD01) as active substance, and it stimulates active immunity against bovine herpesvirus type 1.

The benefit of DIVENCE IBR Marker Live is the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia and clinical signs of IBR (infectious bovine rhinotracheitis).

The most common side effects are injection site inflammation and elevated temperature.

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 Divence IBR Marker Live 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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