16 February 2024
EMA/CVMP/43998/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Divence Penta

Common name: Bovine viral diarrhoea virus type 1 and type 2 (subunit, recombinant), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine

On 13-14 February 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 Penta, lyophilisate and solvent for emulsion for injection, intended for cattle. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Divence Penta is a multi-valent vaccine medicinal product containing live bovine respiratory syncytial virus, strain LYM-56, live gE- tk- double-gene deleted infectious bovine rhinotracheitis virus, strain CEDDEL, inactivated bovine parainfluenza virus 3, strain SF-4 Reisinger, E2 recombinant protein from bovine viral diarrhoea virus 1 and E2 recombinant protein from bovine viral diarrhoea virus 2 (ATCvet code QI02AH) as active substances.

The benefits of Divence Penta are the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia, clinical signs and lung lesions caused by bovine respiratory syncytial virus and parainfluenza virus 3; to reduce virus shedding, hyperthermia and clinical signs caused by infectious bovine rhinotracheitis virus; to reduce viremia, hyperthermia and leukopenia caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2 and virus shedding caused by bovine viral diarrhoea virus 2; and the active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of viral diarrhoea virus (type 1 and 2).

Divence Penta is generally well tolerated at the recommended dose, the most common side effects after vaccination are transient injection site inflammation and increase in body 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

[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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Commission.

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