14 March 2025
EMA/CVMP/82379/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Hepizovac

Common name: Epizootic haemorrhagic disease vaccine (inactivated)

On 13 March 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Hepizovac, a suspension for injection, intended for cattle. The applicant for this veterinary medicinal product is CZ Vaccines S.A.U. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Hepizovac is a vaccine containing inactivated epizootic haemorrhagic disease virus, serotype 8, strain EHDV8 SPA 2022/LCV_03 LCV Cod.:078 (ATCvet code QI02AA) as active substance. The vaccine is intended to stimulate the active immunity of cattle against epizootic haemorrhagic disease virus, serotype 8.

The benefits of Hepizovac are its efficacy for the active immunisation of cattle to prevent viraemia caused by serotype 8 of the epizootic haemorrhagic disease virus.

The most common side effects are injection site inflammation, injection site nodule, injection site pain and elevated temperature (very common).

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 Hepizovac and therefore recommends the granting of the marketing authorisation under exceptional circumstances[3].

[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.
[3] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

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