5 December 2025
EMA/CVMP/368551/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A.

Common name: Epizootic haemorrhagic disease vaccine (recombinant protein)

On 4 December 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 Epizootic haemorrhagic disease vaccine (recombinant protein) - Laboratorios Syva S.A., emulsion for injection for cattle. The applicant for this veterinary medicinal product is Laboratorios Syva S.A. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Epizootic haemorrhagic disease vaccine (recombinant protein) - Laboratorios Syva S.A. is a vaccine containing the recombinant VP2 protein of the Epizootic haemorrhagic disease virus, serotype 8 as active substance. The vaccine is intended to stimulate the active immunity of cattle against epizootic haemorrhagic disease virus, serotype 8.

The benefits of Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A. are its efficacy for the active immunisation of cattle to reduce viraemia and fever caused by serotype 8 of the epizootic haemorrhagic disease virus.

The most common side effects are injection site warmth, injection site nodule, injection site swelling, fever and decreased activity (very common).

The full indication is for active immunisation of cattle to reduce viraemia and fever caused by epizootic haemorrhagic disease virus serotype 8. The onset of immunity is 2 weeks. The duration of immunity

[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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has not been established.

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 Epizootic haemorrhagic disease vaccine (recombinant protein) Laboratorios Syva S.A. and therefore recommends the granting of the marketing authorisation under exceptional circumstances[3].

[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.