



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2025
EMAVRA0000255727 - Summary of Opinion
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion¹ (post-authorisation)

Bluevac BTV

Vaccine common name: Bluetongue virus vaccine (inactivated)

On 15 May 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Bluevac BTV. The marketing authorisation holder for this veterinary medicinal product is CZ Vaccines S.A.U.

Bluevac BTV is currently authorised as a suspension for injection. The variation concerns:

- A new posology (change to the posology for sheep, to vaccinate with one single dose of the bivalent vaccine BTV1+4).

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 Union Product Database (UPD) 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 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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