24 May 2024
EMA/CVMP/183632/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Bluevac BTV

Common name: Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3)

On 22 May 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations 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 variations are to change the multistrain dossier to allow up to two different inactivated bluetongue virus serotypes in the final product (bivalent vaccine) and to implement quality changes.

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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