25 May 2020
EMA/CVMP/235910/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Zulvac BTV

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

On 20 May 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Zulvac BTV. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Zulvac BTV is currently authorised as suspension for injection. The variation concerns the variation of the existing multi-strain dossier in order to allow the use of the current monovalent vaccine against serotype 4 in cattle. The MAH is taking the opportunity to update Annex II of the product information.

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 revised European public assessment report (EPAR) 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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