7 December 2018
EMA/CVMP/808341/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Zulvac BTV (formerly Zulvac BTV Ovis)

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

On 4-6 December 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Zulvac BTV (formerly Zulvac BTV Ovis). The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium S.A.

Zulvac BTV Ovis is currently authorised as a suspension for injection for the active immunisation of sheep (subcutaneous use) from 6 weeks of age for the prevention of viraemia caused by bluetongue virus serotype 1 or serotype 8; or for the reduction of viraemia caused by bluetongue virus serotype 4.

The extension concerns adding cattle as a new food-producing target animal species. The additional indication is for the active immunisation of cattle (intramuscular use) from 12 weeks of age for the prevention of viraemia caused by bluetongue virus, serotype 1 or serotype 8. As a consequence of the extension procedure, the name of the product is changing from Zulvac BTV Ovis to Zulvac BTV.

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 extension 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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