17 February 2017
EMA/CVMP/50456/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Zulvac BTV Ovis

Common name: Bluetongue vaccine (inactivated)

On16 February 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Zulvac BTV Ovis, solution for injection, intended for active immunisation of sheep from 1.5 months of age for the prevention of viraemia caused by bluetongue virus (BTV), serotypes 1 and 8, and for the reduction of viraemia caused by bluetongue virus, serotype 4. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Zulvac BTV Ovis is an immunological veterinary medicinal product containing one strain of inactivated bluetongue virus of the following three strains as active substance: BTV serotype 1, BTV serotype 4 and BTV serotype 8 (ATCvet code QI04AA02). The benefits of Zulvac BTV Ovis is its prophylactic immunisation in sheep from 6 weeks of age for the prevention of viraemia caused by bluetongue virus, serotypes 1 or 8, and the reduction of viraemia caused by bluetongue virus serotype 4. Onset of immunity is established at 21 days with a duration of immunity of 12 months.

The most common side effects are a transient increase in rectal temperature, not exceeding 1.6 °C, during the 48 hours following vaccination. Vaccination may be followed by a transient local reaction at the injection site.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 Zulvac BTV Ovis and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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