18 July 2025
EMADOC-1700519818-2241723
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Syvazul BTV 3

Common name: Bluetongue virus vaccine (inactivated)

On 17 July 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the approval of a variation to the terms of the marketing authorisation for the veterinary medicinal product Syvazul BTV 3. The marketing authorisation holder for this veterinary medicinal product is Laboratorios Syva S.A.

Syvazul BTV 3 is currently authorised for the active immunisation of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue serotype 3. The variation concerns to add cattle as target species, including an increase of the minimum specification for antigen content in the finished product. The changes are reflected in the PI in the corresponding sections as:

Indication of cattle as target species: 'for active immunisation of cattle to reduce viraemia caused by bluetongue serotype 3. Onset of immunity: 3 weeks after completion of the primary vaccination scheme. The duration of immunity has not been established.'

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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