



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2025
EMA/596315/2024
Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Syvazul BTV 3

Common name: Bluetongue virus vaccine (inactivated)

On 15 January 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Syvazul BTV 3, Suspension for injection, intended for sheep. The applicant for this veterinary medicinal product is Laboratorios Syva S.A

Syvazul BTV 3 is a vaccine containing Bluetongue virus, serotype 3, BTV-3/NET2023, Inactivated (ATCvet code QI04AA02) as active substance. It is intended for the active immunisation of sheep against bluetongue virus serotype 3.

The benefits of Syvazul BTV 3 for sheep are to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue serotype 3.

The most common side effects are injection site reaction, injection site erythema, injection site oedema, injection site nodule and elevated temperature.

The full indication is:

For active immunisation of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue serotype 3.

Onset of immunity: 4 weeks after completion of the primary vaccination scheme.

The duration of immunity has not been established.

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.



Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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 Syvazul BTV 3 and therefore recommends the granting of the marketing authorisation under exceptional circumstances³.

³ Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.