22 May 2026
EMADOC-1700519818-3149659
Committee for Veterinary Medicinal Products (CVMP)

**Summary of opinion[1] (post-authorisation)**

# BTVPUR

## Common name: Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4)

On 21 May 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product BTVPUR. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

BTVPUR is currently authorised for the active immunisation of sheep to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes); for the active immunisation of cattle to prevent viraemia caused by bluetongue virus serotypes 1, 2, 4 and/or 8, and to reduce clinical signs caused by bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes).

The variation concerns to update the product information by including a new vaccination practice against BTV8 in sheep. The modified therapeutic indication for sheep is below:

"Active immunisation of sheep to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes).

For bluetongue virus serotype 8 in sheep (monovalent or in combination with serotypes 2–8 or 4–8), when only one injection is administered, the level of protection is limited to the reduction of viraemia and the reduction of clinical signs. Two injections are required for the prevention of viraemia."

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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