21 April 2023
EMA/CVMP/168333/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Proteq West Nile

Common name: West Nile fever vaccine (live recombinant)

On 20 April 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Proteq West Nile. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Proteq West Nile is currently authorised as suspension for injection. The variation concerns the alignment of the product information with version 9.0 of the QRD template and to update the product information to implement the outcome of signal detection activities:
- addition of 'injection site abscess' with a very rare frequency in section 3.6 Adverse events.

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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