10 October 2025
EMA/CVMP/308157/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Lenivia

International non-proprietary name (INN): izenivetmab

On 9 October 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Lenivia, a solution for injection, intended for dogs. The applicant for this veterinary medicinal product is Zoetis Belgium.

Lenivia is an analgesic veterinary medicinal product containing izenivetmab (ATCvet code QN02BG93) as the active substance, which is a caninised monoclonal antibody targeting nerve growth factor (NGF). NGF binds to TrkA receptors located on immune cells to elicit the release of additional proinflammatory mediators, including NGF itself. These inflammatory mediators lead to further peripheral sensitisation involved in pain perception. The inhibition of NGF was demonstrated to provide relief from pain associated with osteoarthritis.

The benefits of Lenivia are its efficacy in reduction of pain associated with osteoarthritis in dogs, which was evaluated in two exploratory dose determination studies and one placebo-controlled clinical trial conducted in accordance with GCP. In the pivotal clinical trial, administration of Lenivia at the proposed dosing interval (0.05 – 0.1 mg/kg) increased the owner-assessed treatment success and resulted in overall improvement of a veterinary categorical assessment in dogs with OA for 90 days, compared to dogs that were administered placebo.

The most common side effects are immediate pain upon injection (common), ataxia, polydipsia, polyuria (uncommon), and lethargy and anorexia (rare).

The full indication is: "For the reduction of pain associated with osteoarthritis (OA) in dogs."

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.

[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Lenivia and therefore recommends the granting of the marketing authorisation.