

13 June 2025 EMA/CVMP/179106/2025 Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Zenrelia

International non-proprietary name (INN): Ilunocitinib

On 12 June 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Zenrelia, film-coated tablets, intended for dogs. The applicant for this veterinary medicinal product is Elanco GmbH.

Zenrelia is a dermatological medicinal product containing ilunocitinib (ATCvet code QD11AH92) as the active substance. Ilunocitinib is a Janus kinase (JAK) inhibitor. It inhibits the function of a variety of pruritogenic and pro-inflammatory cytokines, as well as cytokines involved in allergies which are dependent on JAK enzyme activity. Ilunocitinib has minimal impact on other protein and lipid kinases and has therefore limited risk of off-target effects.

The benefits of Zenrelia are its efficacy in the treatment of pruritus associated with allergic dermatitis in dogs, and in the treatment of clinical manifestations of atopic dermatitis in dogs.

The most common side effects are emesis, diarrhoea and lethargy.

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 Zenrelia and therefore recommends the granting of the marketing authorisation.

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.



 $^{^{}m 1}$ Summaries of opinion are published without prejudice to the Commission Decision.