13 June 2025
EMA/CVMP/179581/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Numelvi

International non-proprietary name (INN): Atinvicitinib

On 12 June 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 Numelvi, tablets, intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V..

Numelvi is a dermatological medicinal product containing atinvicitinib (ATCvet code QD11AH93) as the active substance. Atinvicitinib is a selective Janus kinase (JAK) inhibitor, highly selective for JAK1. It inhibits the function of a variety of cytokines involved in itch and inflammation, as well as cytokines involved in allergy, that are dependent on JAK1 enzyme activity. Reduction of allergy mediated inflammation, which is dependent on JAK1 enzyme activity, leads to a reduction of inflammation associated white blood cell counts (within the reference range).

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

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

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 Numelvi and therefore recommends the granting of the marketing authorisation.

[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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