14 February 2025
EMA/CVMP/43175/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Elmaro

International non-proprietary name (INN): Maropitant

On 12 February 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 Elmaro 10 mg/ml solution for injection for cats and dogs. The applicant for this veterinary medicinal product is Elanco GmbH.

Elmaro is an anti-emetic medicinal product containing maropitant citrate monohydrate (ATCvet code QA04AD90) as active substance, a neurokinin (NK1) antagonist which acts in the central nervous system (CNS) by inhibiting substance P, the key neurotransmitter involved in vomiting.

Elmaro is a generic of Cerenia, which has been authorised in the EU since 29 June 2006. Studies have demonstrated the satisfactory quality of Elmaro and its bioequivalence to the reference product Cerenia.

The target species are dogs and cats. The full indication in dogs is for the treatment and prevention of nausea induced by chemotherapy, for the prevention of vomiting (except that induced by motion sickness), for the treatment of vomiting (in combination with other supportive measures), and for the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine. The full indication in cats is for the prevention of vomiting and the reduction of nausea (except that induced by motion sickness), and for the treatment of vomiting, in combination with other supportive measures.

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 Elmaro 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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