13 April 2015
EMA/CVMP/180883/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Cerenia

International non-proprietary name (INN): Maropitant

On 10 April 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Cerenia. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium S.A.

Cerenia is currently authorised as tablets for dogs, and as a solution for injection for dogs and cats to be administered subcutaneously.

The extension concerns the addition of a new route of administration (intravenous use) for the solution for injection for the existing target species, dogs and cats.

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for the intravenous use of Cerenia 10 mg/ml solution for injection for dogs and cats and therefore recommends the granting of the extension 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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